

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Joel Schneider,
Magistrate Judge

**COMPENDIUM OF UNREPORTED OR UNPUBLISHED AUTHORITIES
CITED IN MANUFACTURER DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION TO DISMISS**

TABLE OF CONTENTS

Cases	Tab
<i>Abicht v. Pliva, Inc.</i> , No. 12-1278, 2013 WL 141724 (D. Minn. Jan. 9, 2013)	1
<i>Amarin Pharma, Inc. v. Int'l Trade Comm'n</i> , Nos. 2018-1247, 2018-114 (Fed. Cir. Mar. 27, 2018) (Corrected Brief for the United States as Amicus Curiae Supporting Appellee)	2
<i>Amarin Pharma, Inc. v. International Trade Com'n</i> , No. 19-152, 2019 WL 5784708 (U.S. Nov. 4, 2019) (Brief of Federal Respondent in Oppsition).....	3
<i>Avram v. Samsung Electronics Am., Inc.</i> , Nos. 2:11-6973, 2:12-976, 2013 WL 3654090 (D.N.J. July 11, 2013)	4
<i>Becker v. Smith & Nephew, Inc.</i> , No. 14-5452, 2015 WL 268857 (D.N.J. Jan. 20, 2015)	5
<i>Bell v. Boehringer Ingelheim Pharm., Inc.</i> No. 17-1153, 2018 WL 928237 (W.D. Pa. Feb. 15, 2018).....	6
<i>Bowman v. RAM Med., Inc.</i> , No. 10-4403, 2012 WL 1964452 (D.N.J. May 31, 2012).....	7
<i>Boyd v. Johnson & Johnson Consumers Cos., Inc.</i> , No. 09-cv-3135, 2010 WL 2265317 (D.N.J. May 31, 2010)	8
<i>Calender v. NVR Inc.</i> , 548 F. App'x 761 (3d Cir. 2013)	9
<i>Cole v. NIBCO, Inc.</i> , No. 3:13-cv-07871, 2015 WL 2414740 (D.N.J. May 20, 2015).....	10
<i>Cooper v. Medimetriks Pharms., Inc.</i> , No. 18-11987, 2019 WL 1370414 (D.N.J. Mar. 25, 2019)	11
<i>Crouch v. Johnson & Johnson Consumer Cos., Inc.</i> , No. 09-cv-2905, 2010 WL 1530152 (D.N.J. Apr. 15, 2010)	12
<i>D'Addario v. Johnson & Johnson</i> , No. 3:10-cv-15627, 2020 WL 3546750 (D.N.J. June 30, 2020).....	13

<i>Danon v. Vanguard Grp., Inc.</i> , 686 Fed. App'x 101 (3d Cir. 2017)	14
<i>Donovan v. Pub. Policy Ctr. of New Jersey</i> , No. 05-1181, 2006 WL 1373230 (D.N.J. May 17, 2006)	15
<i>Dopico v. IMS Trading Corp.</i> , No. 14-cv-1874, 2018 WL 4489677 (D.N.J. Sept. 18, 2018).....	16
<i>Dunbar v. Medtronic, Inc.</i> , No. 14-01529, 2014 WL 3056026 (C.D. Cal. June 25, 2014)	17
<i>Fishman v. Gen. Elec. Co.</i> , No. 2:12-cv-00585, 2013 WL 1845615 (D.N.J. Apr. 30, 2013)	18
<i>Forslund v. Stryker Corp.</i> , No. 09-2134, 2010 WL 3905854 (D. Minn. Sept. 30, 2010).....	19
<i>Glick v. Leatt Corp.</i> , No. 4:17-cv-00291, 2018 WL 9439696 (S.D. Iowa May 3, 2018), aff'd sub nom. <i>Glick v. W. Power Sports, Inc.</i> , 944 F.3d 714 (8th Cir. 2019).....	20
<i>Hammer v. Vital Pharms., Inc.</i> , No. 11-4124, 2012 WL 1018842 (D.N.J. Mar. 26, 2012).....	21
<i>Hoffman v. Nutraceutical Corp.</i> , No. 12-5803, 2013 WL 2650611 (D.N.J. June 10, 2013)	22
<i>Horowitz v. AT&T, Inc.</i> , No. 3:17-cv-4827, 2018 WL 1942525 (D.N.J. Apr. 25, 2018).....	23
<i>Hubert v. Gen. Nutrition Corp.</i> , No. 2:15-cv-01391, 2017 WL 3971912 (W.D. Pa. Sept. 8, 2017)	24
<i>In re Bard IVC Filters Prods. Liab. Litig.</i> , No. 15-md-02641, 2018 WL 4356638 (D. Ariz. Sept. 12, 2018).....	25
<i>In re Digitek Prods. Liab. Litig.</i> , No. 2:08-md-01968, 2009 WL 2433468 (S.D. W. Va. Aug. 3, 2009).....	26
<i>In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)</i> , No. 08-008, 2011 WL 5903623 (D.N.J. Nov. 21, 2011).....	27

<i>In re Gen. Motors LLC Ignition Switch Litig.</i> , No. 14-md-2543 JMF, 2015 WL 3619584 (S.D.N.Y. June 10, 2015).....	28
<i>In re Katrina Canal Breaches Litig.</i> , 309 F. App'x 836 (5th Cir. 2009)	29
<i>In re Magnesium Oxide Antitrust Litig.</i> , No. 10-cv-5943, 2011 WL 5008090 (D.N.J. Oct. 20, 2011)	30
<i>In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.</i> , No. 11-c-5468, 2012 WL 3582708 (N.D. Ill. Aug. 16, 2012).....	31
<i>Iowa Network Servs. v. AT&T Corp.</i> , No. 3:14-cv-3439, 2019 WL 4861438 (D.N.J. Oct. 2, 2019)	32
<i>James v. Johnson & Johnson Consumer Cos., Inc.</i> , No. 2:10-cv-03049, 2011 WL 198026 (D.N.J. Jan. 20, 2011)	33
<i>Koronthaly v. L'Oreal USA, Inc.</i> , 374 F. App'x 257 (3d Cir. 2010)	34
<i>Leonard v. Medtronic, Inc.</i> , No. 1:10-cv-03787-JEC, 2011 WL 3652311 (N.D. Ga. Aug. 19, 2011).....	35
<i>Levinson v. Johnson & Johnson Consumer Cos., Inc.</i> , No. 09-cv-3317, 2010 WL 421091 (D.N.J. Feb. 1, 2010).....	36
<i>Markland v. Insys Therapeutics, Inc.</i> , 758 F. App'x 777 (11th Cir. 2018)	37
<i>MDNet, Inc. v. Parmacia Corp.</i> , 147 F. App'x 239 (3d Cir. 2005).....	38
<i>Medley v. Johnson & Johnson Consumer Cos.</i> , No. 2:10-cv-2291, 2011 WL 159674 (D.N.J. Jan. 18, 2011)	39
<i>Monk v. Wyeth Pharm., Inc.</i> , No. 16-cv-1273, 2017 WL 2063008 (W.D. Tex. May 11, 2017).....	40
<i>Moore v. Medeva Pharm., Inc.</i> , No. 01-311-M, 2004 WL 57084 (D.N.H. Jan. 13, 2004)	41
<i>Sheeran v. Blyth Shipholding S.A.</i> , No. 1:14-cv-5482, 2015 WL 9048979 (D.N.J. Dec. 16, 2016)	42

<i>Sich v. Pfizer Pharm.</i> , No. 1:17-cv-2828, 2017 WL 4407930 (D.N.J. Oct. 4, 2017).....	43
<i>Simmons v. Stryker Corp.</i> , No 08-3451, 2008 WL 4936982 (D.N.J. Nov. 17, 2008).....	44
<i>Sweezey v. C.R. Bard Inc.</i> , No. 3:19-cv-2172, 2020 WL 1237394 (N.D. Tex. Mar. 12, 2020).....	45
<i>Thornton v. AstraZeneca Pharm. LP</i> , No. 1:17-cv-652, 2017 WL 2255776 (N.D. Ga. May 15, 2017)	46
<i>Torres-Hernandez v. CVT Prepaid Sols., Inc.</i> , No. 3:08-cv-1057, 2008 WL 5381227 (D.N.J. Dec. 17, 2008)	47
<i>Walters v. Carson</i> , No. 11-6545, 2012 WL 6595732 (D.N.J. Dec. 17, 2012).....	48

TAB 1

 KeyCite Yellow Flag - Negative Treatment
Disagreed With by [Phelps v. Wyeth, Inc.](#), D.Or., April 2, 2013
2013 WL 141724

United States District Court, D. Minnesota.

Marilyn ABICHT, Plaintiff,
v.
PLIVA, INC., Defendant.
Stephen White,
v.
PLIVA, Inc., Defendant.

Civ. Nos. 12-1278 (PAM/JJG), 12-2172 (PAM/JJG).

|
Jan. 9, 2013.

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MEMORANDUM AND ORDER

[PAUL A. MAGNUSON](#), District Judge.

***1** This matter is before the Court on Defendant PLIVA, Inc.'s Motions for Judgment on the Pleadings in these related cases. For the reasons that follow, the Motions are granted.

BACKGROUND

Plaintiff Marilyn Abicht was prescribed the drug [Reglan](#) for digestive tract issues beginning in 1998, and took it until 2008. During that time, she was often given [Reglan's](#) generic equivalent, [metoclopramide](#), that was manufactured by Defendant PLIVA, Inc. She developed a serious [neurological disorder](#) called [tardive dyskinesia](#) as a result of her use of [metoclopramide](#). [Tardive dyskinesia](#) "is a severe and often permanent disfiguring neurological movement disorder." [Bowman v. Wyeth, LLC](#), No. 10-1946, 2012 WL 684116, at * 1 n. 1 (D.Minn. Mar. 2, 2012) (Erickson, J.).

Plaintiff Steven White also took [Reglan](#) or [metoclopramide](#) starting in 1998. He stopped taking [metoclopramide](#) in 2009. He has also been diagnosed as suffering from [tardive dyskinesia](#) brought on by his use of the drug.

There is no dispute that long-term use of [metoclopramide](#) can cause [tardive dyskinesia](#), such that since 2009 the label for both [Reglan](#) and the generic versions¹ contain the following warning: "Treatment with [metoclopramide](#) can cause [tardive dyskinesia](#), a serious movement disorder that is often irreversible.... Treatment with [metoclopramide](#) for longer than 12 weeks should be avoided in all but rare cases." Physician's Desk Reference 2902 (65th ed.2011). As early as 1995, however, the label provided that "[tardive dyskinesia](#) ... may develop in patients treated with [metoclopramide](#)" and "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." Physician's Desk Reference 1635-36 (41st ed.1987). In 2004 the FDA approved a stronger warning on [Reglan's](#) label that use "should not exceed 12 weeks in duration." [PLIVA, Inc. v. Mensing](#), —U.S. —, — — —, 131 S.Ct. 2567, 2572-73, 180 L.Ed.2d 580 (2011) (quotation omitted). Plaintiffs both contend that PLIVA failed to update the label for its version of [metoclopramide](#) to include this warning, among other claims.² The causes of action they raise include strict liability, breach of warranties, negligence, misrepresentation, fraud, negligence *per se*, Minnesota Deceptive Trade Practices Act, Minnesota Prevention of Consumer Fraud Act, and negligent infliction of emotional distress.

¹ Under the Hatch-Waxman Amendments to the Food Drug & Cosmetic Act ("FDCA"), generic equivalents are required to have the same label as the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(v).

² Plaintiffs also contend that a 2003 label update was likewise not included in PLIVA's labeling. But this update involved the use of [metoclopramide](#) for pediatric and geriatric patients, and there is no evidence that either Abicht or White were very young or very old when they took [metoclopramide](#).

DISCUSSION

A motion for judgment on the pleadings under Fed.R.Civ.P. 12(c) is analyzed according to the same standards as a motion to dismiss under Rule 12(b)(6). [Westcott v. Omaha](#), 901 F.2d 1486, 1488 (8th Cir.1990). The Court must construe the allegations in the pleadings and reasonable inferences arising from the pleadings favorably to the non-moving party. [Morton](#)

v. Becker, 793 F.2d 185, 187 (8th Cir.1986). The Court should not, however, “blindly accept the legal conclusions drawn by the pleader from the facts.” *Id.* A motion for judgment on the pleadings will be granted only if “it appears beyond doubt that the [nonmovants] can prove no set of facts which would entitle [them] to relief.” *Id.*; *see also Conley v. Gibson*, 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957).

A. Preemption and *Mensing*

*2 The Supreme Court recently determined that an individual suffering from *tardive dyskinesia* as a result of her long-term use of *metoclopramide* could not bring state-law claims against PLIVA for failure to warn of the risks of *metoclopramide*. *PLIVA, Inc. v. Mensing*, — U.S. —, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011). Under the doctrine of impossibility preemption, the Court found that state-law duties that ostensibly required a generic drug's manufacturer to include stronger warnings on its label than those approved by the FDA for the brand-name drug were preempted, because the FDA required a generic drug's label to be the same as the brandname drug's label. Thus, it was impossible for a generic drug manufacturer to comply with state law and with federal law.

PLIVA argues here that this case is identical to *Mensing* and must be dismissed as preempted. And, to be sure, most of Plaintiffs' claims in these two cases are just the sort of failure-to-warn claims that *Mensing* prohibits, whether couched as strict liability, breach of warranties, negligence, misrepresentation, fraud, negligence *per se*, Minnesota Deceptive Trade Practices Act, Minnesota Prevention of Consumer Fraud Act, or negligent infliction of emotional distress, and those claims must be dismissed as preempted by *Mensing*. But Plaintiffs also raise a different claim, one that *Mensing* did not address: are claims that a generic drug failed to include warnings that the brand-name drug's label contained cognizable under state law?

B. “Sameness”

Plaintiffs base their failure-to-update claim on the FDA's requirement that “generic drug manufacturers have an ongoing federal duty of ‘sameness.’ ” *Mensing*, 131 S.Ct. at 2575. They contend that PLIVA's alleged failure to comply with this duty gives rise to claims under state law. But if the duty involved is a federal duty—and Plaintiffs do not argue that state law does or even could impose any duty of sameness—then that duty is enforceable only through federal law, not state law. And federal law not only expressly

preempts state law but also precludes any private cause of action for enforcement of the FDA's requirements. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 532 U.S. 341, 349 n.4 (2001) (“The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit....”); *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 776–77 (D.Minn.2009) (Schiltz, J.) (“Thus, a private litigant cannot sue a defendant for violating the FDCA.”).

Federal law is the gravamen of Plaintiffs' failure-to-update claim here. They contend that PLIVA violated its duties under the FDCA by failing to include on the metoclopramide label the information the FDA approved for *Reglan*'s label. But the enforcement of such a duty is exclusively the province of the federal government, not of state tort law. “[A] private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist.” *Riley*, 625 F.Supp.2d at 777.

*3 Plaintiffs cite a litany of cases in support of their argument that a claim regarding a failure to update a drug's label is not preempted. Plaintiffs at times misrepresent the holdings in the cases they cite, and in any event most of them are not on point. For example, Plaintiffs contend that one case found “claims based on generic manufacturer's failure to upgrade to the current label may not be preempted.” (Pl.'s Opp'n Mem. (12-1278 Docket No. 19) at 18 (citing *Metz v. Wyeth, LLC*, No. 8:10cv2658, 2012 WL 1058870, at *8 (M.D.Fla. Mar.28, 2012)).) But *Metz* did not involve a claim regarding a manufacturer's failure to update a label. Rather, the plaintiffs in *Metz* claimed that the generic drug manufacturer failed adequately to communicate to physicians the warning in the 2004 label update. The court in *Metz* stated that it might not be impossible for the manufacturer to comply with its federal duties and “to more effectively communicate the FDA approved label to medical providers and/or consumers” as state law ostensibly required, and therefore that *Mensing* did not necessarily preempt this particular claim. *Metz*, 2012 WL 1058870, at *3. However, even if not preempted, those claims were barred by Florida law. *Id.* at *8.

Nor does the Eighth Circuit Court of Appeals' holding in *Lefavre v. KV Pharmaceutical Company*, 636 F.3d 935 (8th Cir.2011), compel a different conclusion. Although the *Lefavre* decision takes a narrow view of preemption under the FDCA, that decision issued several months before the Supreme Court's *Mensing* decision. Not only did *Mensing*

take a much broader view of FDCA preemption, especially when applied to a generic drug manufacturer's duty with respect to drug labeling, but the Supreme Court in *Mensing* also struck down the Eighth Circuit's own narrower FDCA preemption analysis. Thus, to the extent that *Lefaire* is on point, it is not persuasive in this situation.

To be certain, there are some decisions finding that claims regarding the failure to update a drug's labeling may not be preempted under *Mensing*. See, e.g., *Fisher v. Pelstring*, 817 F.Supp.2d 791, 805 (D.S.C.2011). According to *Fisher*, "a negligence action in which the standard of care is defined by statute is [not] the equivalent of private enforcement of the FDCA." *Id.* at 834. This Court respectfully disagrees with the *Fisher* court's analysis. Where federal law supplies the duty, a state claim to enforce that duty is, in substance if not in form, a cause of action under federal law. And such private actions are not allowed under the FDCA. As such, Plaintiffs' failure-to-update claim fails as a matter of law.

CONCLUSION

Accordingly, **IT IS HEREBY ORDERED that:**

1. PLIVA's Motion for Judgment on the Pleadings in Civ. No. 12-1278 (Docket No. 14) is **GRANTED**;
2. PLIVA's Motion for Judgment on the Pleadings in Civ. No. 12-2172 (Docket No. 11) is **GRANTED**; and

***4 3. These cases are DISMISSED with prejudice.**

LET JUDGMENT BE ENTERED ACCORDINGLY.

All Citations

Not Reported in F.Supp.2d, 2013 WL 141724, Prod.Liab.Rep. (CCH) P 19,015

TAB 2

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LTD.,

Appellants,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

ROYAL DSM NV, DSM MARINE LIPIDS PERU S.A.C, DSM NUTRITIONAL
PRODUCTS LLC, DSM NUTRITIONAL PRODUCTS CANADA, INC.,
PHARMAVITE LLC, NORDIC NATURALS, INC., NORDIC PHARMA, INC.,

Intervenors.

On Appeal from the United States International
Trade Commission, No. 3247.
(caption continued on inside cover)

**CORRECTED BRIEF FOR THE UNITED STATES AS
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(caption continued from front cover)
In re: AMARIN PHARMA, INC.,
AMARIN PHARMACEUTICALS IRELAND LTD.,

Petitioners,

On Petition for Writ of Mandamus to the
United States International Trade Commission

TABLE OF CONTENTS

	<u>Page</u>
INTEREST OF THE UNITED STATES.....	1
STATEMENT OF THE CASE.....	2
A. FDA Regulation of Drugs and Dietary Supplements.....	2
B. The International Trade Commission.....	4
C. Factual Background and Proceedings Below.....	5
SUMMARY OF ARGUMENT.....	7
ARGUMENT: The Federal Food, Drug, and Cosmetic Act Precludes Private Enforcement Proceedings Like Amarin's.....	8
A. Amarin's Claims Are Private Attempts to Enforce the FDCA, and Are Therefore Prohibited.....	8
B. Amarin's Arguments Are Without Merit.....	21
CONCLUSION.....	29
CERTIFICATE OF COMPLIANCE	
CERTIFICATE OF SERVICE	

TABLE OF AUTHORITIES

Cases:	<u>Page(s)</u>
<i>Allergan, Inc. v. Athena Cosmetics, Inc.</i> , 738 F.3d 1350 (Fed. Cir. 2013).....	8, 9, 24, 25, 26, 27
<i>Alpharma, Inc. v. Pennfield Oil Co.</i> , 411 F.3d 934 (8th Cir. 2005)	20
<i>Baden Sports, Inc. v. Molten USA, Inc.</i> , 556 F.3d 1300 (Fed. Cir. 2009).....	12
<i>Buckman Co. v. Plaintiffs' Legal Comm.</i> , 531 U.S. 341 (2001).....	1, 3, 8, 10, 25
<i>Clock Spring, LP v. Wrapmaster, Inc.</i> , 560 F.3d 1317 (Fed. Cir. 2009).....	17
<i>Cottrell, Ltd. v. Biotrol Int'l, Inc.</i> , 191 F.3d 1248 (10th Cir. 1999)	21
<i>Dastar Corp. v. Twentieth Century Fox Film Corp.</i> , 539 U.S. 23 (2003).....	12
<i>Dial A Car, Inc. v. Transp., Inc.</i> , 82 F.3d 484 (D.C. Cir. 1996).....	20-21
<i>Heckler v. Chaney</i> , 470 U.S. 821 (1985).....	10
<i>Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc.</i> , 230 F. Supp. 3d 1323 (N.D. Ga. 2016).....	24
<i>IQ Prods. Co. v. Pennzoil Prods. Co.</i> , 305 F.3d 368 (5th Cir. 2002)	20
<i>Mylan Labs., Inc. v. Matkari</i> , 7 F.3d 1130 (4th Cir. 1993)	19

<i>Mylan Pharm., Inc. v. Thompson</i> , 268 F.3d 1323 (Fed. Cir. 2001), superseded by statute on other grounds as recognized in <i>Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S</i> , 566 U.S. 399, 408 (2012).....	13, 19
<i>PDK Labs, Inc. v. Friedlander</i> , 103 F.3d 1105 (2d Cir. 1997).....	20
<i>PhotoMedex, Inc. v. Irwin</i> , 601 F.3d 919 (9th Cir. 2010)	17, 18
<i>POM Wonderful LLC v. Coca-Cola Co.</i> , 134 S. Ct. 2228 (2014).....	8, 21, 22, 23
<i>RadLAX Gateway Hotel, LLC v. Amalgamated Bank</i> , 566 U.S. 639 (2012).....	11
<i>Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.</i> , 902 F.2d 222 (3d Cir. 1990).....	18-19
<i>ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.</i> , 648 F. App'x 609 (9th Cir. 2016)	23
<i>TianRui Grp. Co. v. Int'l Trade Comm'n</i> , 661 F.3d 1322 (Fed. Cir. 2011).....	13
<i>Ventas, Inc. v. United States</i> , 381 F.3d 1156 (Fed. Cir. 2004).....	9
<i>Wyeth v. Levine</i> , 555 U.S. 555 (2009).....	3

Statutes:

Federal Food, Drug, and Cosmetic Act:

21 U.S.C. § 301 <i>et seq.</i>	2
21 U.S.C. § 321(g)(1)	2, 16
21 U.S.C. § 321(g)(1)(B).....	2
21 U.S.C. § 321(g)(1)(C).....	2
21 U.S.C. § 321(p)(1).....	3

21 U.S.C. § 321(ff).....	15
21 U.S.C. § 321(ff)(1)	2
21 U.S.C. § 321(ff)(3)(B)(ii)	2
21 U.S.C. § 331(a).....	14
21 U.S.C. § 331(d)	3, 14
21 U.S.C. § 332.....	3, 11
21 U.S.C. § 333.....	3
21 U.S.C. § 334(a)(1)	3
21 U.S.C. § 337(a).....	1, 4, 7, 9, 10, 11, 15, 17, 26, 27, 28
21 U.S.C. § 337(b)	9
21 U.S.C. § 342(f)(1)(a)	3
21 U.S.C. § 351.....	14
21 U.S.C. § 352.....	14
21 U.S.C. § 355.....	3, 4, 9
21 U.S.C. § 381(a).....	11, 14
21 U.S.C. § 381(a)(3)	3
21 U.S.C. § 393.....	4, 9
52 Stat. 1040, 1046.....	12
H.R. Rep. No. 2139 (April 14, 1938).....	9
 Lanham Act:	
15 U.S.C. § 1125(a).....	4
15 U.S.C. § 1125(a)(1)(B)	4, 16
 Tariff Act of 1930:	
19 U.S.C. § 1334.....	27
19 U.S.C. § 1337(a)(1)	27, 28
19 U.S.C. § 1337(a)(1)(A)(i)	4, 17
19 U.S.C. § 1337(d)	4
46 Stat. 590, 703	12
28 U.S.C. § 517.....	1
 Sherman Food, Drug, and Cosmetic Law,	
Cal. Health & Safety Code § 109875 <i>et seq.</i>	24
 Unfair Competition Law,	
Cal. Bus. & Prof. Code § 17203.....	24

Rule:

Fed. R. App. P. 29(a)(2).....	1
-------------------------------	---

Other Authorities:

<i>Black's Law Dictionary</i> (10th ed. 2014)	10
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Initial Determination, <i>In re Certain Insulated Sec. Chests</i> , USITC Inv. No. 337-TA-244, 1987 WL 451338 (June 17, 1986)	4
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INTEREST OF THE UNITED STATES

This case presents the question whether private parties may seek to enforce the Federal Food, Drug, and Cosmetic Act (FDCA) through a private proceeding like the complaint that Amarin brought before the International Trade Commission. The United States submits this amicus brief to protect its interest in the proper resolution of that question. *See* 28 U.S.C. § 517; Fed. R. App. P. 29(a)(2).

“The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with” the FDCA. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Private parties are expressly prohibited from bringing “proceedings for the enforcement, or to restrain violations, of” the FDCA. 21 U.S.C. § 337(a). Yet that is precisely what Amarin seeks to do here. Amarin’s claims, though nominally brought under the Tariff Act, attempt to enforce or restrain violations of the FDCA because they seek—as a necessary component of the stated cause of action—to prove FDCA violations and compel obedience to the FDCA through the remedies provided by that statute. For that reason, the International Trade Commission correctly concluded that Amarin’s claims are precluded by the FDCA. The United States takes no position on the other issues in this case.

STATEMENT OF THE CASE

A. FDA Regulation of Drugs and Dietary Supplements

1. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, authorizes the Food and Drug Administration (FDA) to regulate, among other things, drugs and dietary supplements. Determining whether an article is a “drug” or a “dietary supplement” under the FDCA can involve difficult and complex analysis. In general, the term “drug” includes “articles (other than food)” that are “intended to affect the structure or any function of the body of man or other animals,” as well as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.” *Id.* § 321(g)(1)(B), (C). A “dietary supplement” is a product that, among other factors, contains a “dietary ingredient[],” which includes, among other things, a vitamin, mineral, herb, or “a dietary substance for use by man to supplement the diet by increasing the total dietary intake.” *Id.* § 321(ff)(1).

These general definitions are further refined by other provisions of the FDCA. For example, a “dietary supplement” that otherwise might meet the definition of a “drug” is “not a drug * * * solely because” the label contains certain types of health-related claims. 21 U.S.C. § 321(g)(1). And the term “dietary supplement” excludes “an article authorized for investigation as a new drug,” where the investigation has been instituted and made public, unless before such authorization the article was “marketed as a dietary supplement or as a food.” *Id.* § 321(ff)(3)(B)(ii).

The FDCA treats “drugs” and “dietary supplements” differently. Unless a drug is “generally recognized” as “safe and effective for use under the conditions prescribed, recommended, or suggested” in its labeling, it is classified as a “new drug.” 21 U.S.C. § 321(p)(1). And the FDCA prohibits introducing a new drug into interstate commerce before it has been approved by FDA. *Id.* §§ 331(d), 355. To obtain pre-market approval, the drug sponsor has the burden of proving that a new drug is safe and effective for its intended use. *See Wyeth v. Levine*, 555 U.S. 555, 567 (2009). A sponsor that introduces a new drug into interstate commerce without complying with this requirement is subject to a variety of FDA enforcement measures, including criminal penalties (21 U.S.C. § 333), injunctive relief (*id.* § 332), forfeiture (*id.* § 334(a)(1)), and—most relevant here—exclusion of the drug from importation into the United States (*id.* § 381(a)(3)).

By contrast, “dietary supplements” do not require or receive pre-market approval for safety and efficacy. If FDA determines that a dietary supplement is “adulterated” food—because, for example, it “presents a significant or unreasonable risk of illness or injury,” 21 U.S.C. § 342(f)(1)(A)—the manufacturer may be subject to the same range of FDCA enforcement measures applicable to new drugs.

2. “The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with” the FDCA. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Congress gave the Secretary of Health and Human Services and FDA the authority to execute the

requirements of the FDCA. *See* 21 U.S.C. §§ 355, 393. And Congress prohibited private parties from bringing actions to enforce the FDCA: “[A]ll *** proceedings for the enforcement, or to restrain violations, of this chapter shall be *by and in the name of the United States.*” *Id.* § 337(a) (emphasis added).

B. The International Trade Commission

The Tariff Act of 1930 prohibits “[u]nfair methods of competition and unfair acts in the importation of articles” into the United States, where such acts have the “threat or effect” of “destroy[ing] or substantially injur[ing] an industry in the United States.” 19 U.S.C. § 1337(a)(1)(A)(i). Private parties may submit claims under this provision to the International Trade Commission for adjudication. If the Commission finds a violation, it “shall direct that the articles concerned” be “excluded from entry into the United States.” *Id.* § 1337(d).

The Tariff Act does not fully define what constitutes an “unfair act” or “unfair method of competition.” Through adjudication, the Commission has interpreted those terms to include conduct violating the false-advertising provisions of the Lanham Act, 15 U.S.C. § 1125(a). *See, e.g.*, Initial Determination, *In re Certain Insulated Sec. Chests*, USITC Inv. No. 337-TA-244, 1987 WL 451338, at *2 (June 17, 1986). The Lanham Act prohibits using in commercial advertising any “term” that “misrepresents the nature, characteristics, [or] qualities” of goods. 15 U.S.C. § 1125(a)(1)(B).

C. Factual Background and Proceedings Below

1. Amarin obtained approval from FDA to market a new drug to treat severe hypertriglyceridemia. Appx9, Appx14-15. The drug consists of capsules of an ethyl ester form of eicosapentaenoic acid that is synthetically produced from fish oils. Appx9, Appx11, Appx14-15. Amarin alleges that other manufacturers also synthetically derive eicosapentaenoic acid (and close relatives) and import articles “predominantly comprised” of those ingredients into the United States. Appx9. Those manufacturers allegedly label and market those articles as “dietary supplements,” and also allegedly market them as suitable for treating various diseases. Appx9, Appx11, Appx14-15, Appx17-18.

Amarin filed a complaint with the International Trade Commission, seeking to exclude these articles from the United States under the Tariff Act. Appx4-114. The complaint alleged that the accused articles do not qualify as “dietary supplements” under the FDCA and instead constitute “new drugs,” for which the manufacturers should have, but did not, obtain FDA approval of their safety and efficacy prior to marketing them in the United States, as required by the FDCA. Appx16.

Based on these allegations, Amarin presented two legal claims to the Commission. In one claim, Amarin contended that the importation of the articles violates the Tariff Act “based on the standards set forth in the FDCA.” Appx56; *see* Appx56-59. In other words, Amarin alleged that the articles were marketed in violation of the FDCA, and that importation of articles marketed in violation of the

FDCA is an “unfair act” for that reason. In the other claim, Amarin argued that labeling the articles as “dietary supplements” is an “unfair act” in violation of the Tariff Act because it constitutes false advertising under the Lanham Act. Appx16; *see* Appx31-56. Amarin reasoned that labeling the articles as “dietary supplements” is “literally false” because the articles do not qualify as “dietary supplements” under the FDCA, and it also “hides the material fact that the products are actually unapproved ‘new drugs.’” Appx55.

2. FDA submitted a letter to the Commission asking it to dismiss the complaint. FDA noted that it had not determined whether the articles were drugs or dietary supplements. Appx627. FDA explained that Congress gave FDA enforcement authority over the FDCA and prohibited private parties from bringing proceedings to enforce the FDCA. Appx630. And, FDA explained, the complaint that Amarin filed with the Commission “attempt[s] an unlawful private FDCA enforcement action.” Appx627. Amarin’s claims “all depend on the allegation that the products at issue are falsely labeled as ‘dietary supplements’ because they do not meet the FDCA definition of ‘dietary supplements’ and instead meet the FDCA definition of ‘new drugs.’” Appx631. Accordingly, FDA concluded, “in order to resolve any of [Amarin’s] claims, the Commission will necessarily have to step into the shoes of the FDA,” but “the FDCA precludes such action.” Appx632.

3. The Commission dismissed the complaint. The Commission held that “Amarin’s complaint does not allege an unfair method of competition or an unfair act cognizable under” the Tariff Act. Appx1. The Commission explained that “the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act,” and that “the Food and Drug Administration is charged with the administration of the FDCA.” *Id.*

SUMMARY OF ARGUMENT

A. The International Trade Commission correctly held that the Federal Food, Drug, and Cosmetic Act precludes Amarin’s complaint. The FDCA prohibits private proceedings “for the enforcement, or to restrain violations, of” that statute. 21 U.S.C. § 337(a). The FDCA instead commits enforcement exclusively to the federal government to ensure that complex enforcement decisions are made with the benefit of FDA’s scientific and regulatory expertise. As a consequence, private parties, like Amarin, may not initiate proceedings in a court or administrative agency to remedy alleged violations of the FDCA. Nor can private parties circumvent that prohibition by wrapping their FDCA enforcement claims inside some *other* cause of action. The FDCA prohibits “all” private proceedings to enforce or restrain violations of the FDCA, *id.*, including private claims that are nominally brought under another statute but seek to prove violations of the FDCA and compel obedience to that statute—as the courts of appeals have consistently concluded.

B. Amarin’s arguments to the contrary are without merit. To be sure, private parties may bring suit to remedy violations of statutes that create private causes of action, so long as those suits are *not* attempts to enforce the FDCA. That is why, for example, false advertising about the content of fruit juice can be remedied in a private action under the Lanham Act, where the claim does not seek to prove or remedy a violation of the FDCA’s juice-labeling provisions but instead rests on allegations entirely independent of the FDCA. *See POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014). Nor does the FDCA preempt claims brought under state law that seek to prove and remedy violations of state statutes parallel to but independent of the FDCA. *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013). But where a private party, like Amarin, seeks to prove and remedy violations of the FDCA itself, as a necessary element of its stated cause of action, its claims are precluded by the FDCA’s prohibition on private enforcement proceedings.

ARGUMENT

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT PRECLUDES PRIVATE ENFORCEMENT PROCEEDINGS LIKE AMARIN’S.

A. Amarin’s Claims Are Private Attempts to Enforce the FDCA, and Are Therefore Prohibited.

1. “The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with” the FDCA. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Congress gave the Secretary of Health and Human Services and FDA the authority to execute the

requirements of the FDCA. *See* 21 U.S.C. §§ 355, 393. And Congress expressly provided that “all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be *by and in the name of the United States*”—not private parties. *Id.* § 337(a) (emphasis added); *see* H.R. Rep. No. 2139, at 5 (April 14, 1938).

The only exception to this rule is that “[a] State may bring in its own name and within its jurisdiction proceedings for the civil enforcement” of specific provisions of the FDCA related to food. 21 U.S.C. § 337(b). In narrowly drawing that lone exception, Congress underscored that, otherwise, only the United States may bring “proceedings for the enforcement, or to restrain violations, of” the FDCA. *Id.* § 337(a); *see* *Ventas, Inc. v. United States*, 381 F.3d 1156, 1161 (Fed. Cir. 2004) (“[T]he maxim *expressio unius est exclusio alterius* presumes that [enumerated exceptions] are the only exceptions Congress intended.”). For that reason, this Court has correctly noted that, outside this single exception, “[t]he FDA—and the FDA alone—has the power and the discretion to enforce the FDCA.” *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1359 (Fed. Cir. 2013).

Centralizing FDCA enforcement authority within FDA ensures that FDA’s expertise will inform often-difficult factual and legal determinations, such as which requirements apply to particular articles and whether an article is being distributed in violation of the FDCA. *See* Appellee Br. 27-37 (illustrating the technical issues that would arise in adjudicating Amarin’s claims). It also ensures that discretionary determinations—like whether enforcement measures should be pursued for a

violation, and if so, which remedies are appropriate—will be made by policymakers, not private parties. And it promotes uniformity. Private parties, of course, must reach their own determinations about what the FDCA requires in the first instance, and courts may need to determine if the FDCA has been violated when the federal government brings FDCA enforcement proceedings. But Congress deliberately chose to centralize within FDA the crucial decision whether to seek to prove and redress alleged violations of the FDCA. Doing so maximizes the benefits of centralized enforcement. *Cf. Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (discussing those benefits).

2. The FDCA’s prohibition on private “proceedings for the enforcement, or to restrain violations, of” the Act, 21 U.S.C. § 337(a), means that private parties may not bring suit under the FDCA itself to remedy what they allege to be violations of the Act. It also means that private parties may not circumvent this straightforward prohibition by invoking some *other* cause of action, under another federal statute, in order to bring what is, at bottom, still an action “for the enforcement” or “to restrain violations” of the FDCA. *See Buckman*, 531 U.S. at 353 (preempting state fraud claims that “exist solely by virtue of the FDCA”).

A proceeding “for the enforcement” of the FDCA is one that seeks “[t]o give force or effect” and “compel obedience to” the FDCA. *Black’s Law Dictionary* (10th ed. 2014) (defining “to enforce”). Similarly, a proceeding to “restrain violations” of the FDCA seeks to prove and redress such violations. In order to give meaningful

effect to Congress's mandate that “*all*” such proceedings to enforce or restrain violations of the FDCA “shall be by and in the name of the United States,” 21 U.S.C. § 337(a) (emphasis added), the FDCA precludes those private proceedings that rely on alleged violations of the FDCA as a necessary component of their cause of action and that seek to redress or restrain those FDCA violations. That is particularly clear where the private proceeding seeks remedies like those available under the FDCA, such as injunctive relief, *id.* § 332, or refusal of admission of articles into the United States, *id.* § 381(a).

That conclusion is reinforced by traditional principles of statutory construction. Where “Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions,” and where one such specific solution contradicts a more-general statute, the “specific provision is construed as an exception to the general one” in order to “eliminate the contradiction.” *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012). Here, the FDCA is a highly reticulated regime of requirements for very specific articles—including drugs and dietary supplements—and, as part of that comprehensive scheme to solve particular problems, the FDCA prohibits private proceedings to enforce or restrain violations of the FDCA. By contrast, the Tariff Act states general requirements—no “unfair acts” in the “importation of articles”—that are applicable to a far larger universe of articles, and it creates a private cause of action to enforce those general requirements. The FDCA’s careful prohibition on private enforcement proceedings cannot be fully

implemented if a private party may use the Tariff Act to enforce or restrain violations of the FDCA. Accordingly, the more-specific provisions of the FDCA control.

That conclusion is reinforced by the timeline. When Congress enacted the Tariff Act in 1930, it allowed private parties to file complaints with the Commission alleging “unfair acts” in the importation of articles and seeking to exclude those articles from the United States. *See* 46 Stat. 590, 703. The question whether private parties could use that mechanism to exclude articles alleged to violate the FDCA first arose in 1938, when the FDCA was enacted. And, at that first available opportunity, Congress made clear that its new and specific regulatory regime could not be enforced through private enforcement proceedings of any stripe. *See* 52 Stat. 1040, 1046 (prohibiting “all” private enforcement). Congress thus did not extend the Tariff Act to cover violations of the FDCA; it preferred instead to leave FDCA enforcement to the comprehensive framework it created in that more-specific statute.

The Supreme Court and this Court applied similar reasoning when limiting the scope of the Lanham Act in order to give full force to the Copyright and Patent Acts. These courts held that claims alleging false statements about the authorship of a written work, or origin of an innovation, are not cognizable under the false-advertising provision of the Lanham Act because, among other reasons, entertaining such claims under the Lanham Act would avoid the more-specific regulation of those subjects under the Copyright and Patent Acts. *See Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 33-35 (2003); *Baden Sports, Inc. v. Molten USA, Inc.*, 556 F.3d

1300, 1307 (Fed. Cir. 2009); *see also TianRui Grp. Co. v. Int'l Trade Comm'n*, 661 F.3d

1322, 1333 (Fed. Cir. 2011) (The Tariff Act “cannot be used to circumvent express congressional limitations on the scope of substantive U.S. patent law.”).

Similarly, this Court held in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1332-33 (Fed. Cir. 2001), *superseded by statute on other grounds as recognized in Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012), that a claim nominally seeking declaratory judgment regarding non-liability for patent infringement was actually an improper attempt to privately enforce the FDCA. The plaintiff argued that it should be declared to not be liable for infringement because the defendant had violated a provision of the FDCA. *Id.* Because no cause of action existed to challenge that type of FDCA violation, this Court held that the prohibition on private FDCA enforcement proceedings precluded entertaining the plaintiff’s suit under the Declaratory Judgment and Patent Acts. *Id.*

For these reasons, permitting private parties to enforce and restrain violations of the FDCA using the Tariff Act would permit what Congress prohibited. The specific provisions of the FDCA govern, and they preclude extending the provisions of the earlier and more-general Tariff Act to enforce the FDCA.

3. Both of the claims that Amarin submitted to the International Trade Commission constitute private efforts to enforce or restrain violations of the FDCA, and both are therefore precluded.

a. One of Amarin’s claims contends that the Commission should exclude articles from entry into the United States because those articles allegedly violate several provisions of the FDCA. Amarin claims that the importation of the accused articles is an “unfair act,” within the meaning of the Tariff Act, “*based upon the standards set forth in the FDCA.*” Appx56 (emphasis added). Amarin elaborates that the accused articles are allegedly “misbranded drugs in violation of the standards set forth in Section 502 of the FDCA, [21 U.S.C.] § 352, and adulterated drugs, in violation of Section 501 of the FDCA, *id.* § 351.” Appx57; *see also* Appx57-59 (alleging other violations). Amarin further contends that the introduction of these allegedly adulterated and misbranded drugs “is prohibited by Section 301(d) and (a) of the FDCA[,] [21 U.S.C.] § 331(a), (d).” Appx59. Amarin also explains that “the FDCA prohibits unapproved ‘new drugs,’ and adulterated and misbranded ‘drugs,’ from entering the United States under Section 801(a) of the FDCA, 21 U.S.C. § 381(a),” and argues that, under that provision of the FDCA, FDA “must refuse *** admission to the United States” of unapproved, adulterated, and misbranded drugs. *Id.*

In sum, Amarin seeks to prove a series of alleged FDCA violations and to remedy those violations by excluding unapproved, adulterated, and misbranded drugs from importation into the United States. In advancing this claim, Amarin provides no reason, other than the alleged violations of the FDCA, to conclude that the importation of the accused articles constitutes an “unfair act” within the meaning of

the Tariff Act. Instead, Amarin candidly admits that this claim seeks relief “based upon the standards set forth in the FDCA.” Appx56. For these reasons, Amarin’s claim is a private proceeding “for the enforcement, or to restrain violations, of” the FDCA, 21 U.S.C. § 337(a), and Amarin is therefore prohibited from pursuing that claim.

b. Amarin’s false-advertising claim is no different. In that claim, Amarin contends that the accused articles should be excluded from entry into the United States because labeling on, or advertisements about, those articles is allegedly false or misleading, in violation of the false-advertising provision of the Lanham Act, such that importation of those articles would constitute an “unfair act” under the Tariff Act. Appx31-56. But this claim, too, is expressly predicated on proving, and seeks remedies for, alleged violations of the FDCA.

Amarin contends that labeling on the accused articles “falsely asserts that the products are ‘dietary supplements,’” where the articles “cannot meet the definition of ‘dietary supplement’ in Section 201(ff) of the FDCA, 21 U.S.C. § 321(ff).” Appx33. Amarin’s complaint devotes over twelve pages to identifying provisions of the FDCA that govern what is and is not a “dietary supplement,” alleging facts about the articles, and explaining why, in Amarin’s view, the articles do not meet the FDCA’s definition of “dietary supplement.” Appx34-47. Amarin further alleges that the articles “are actually unapproved ‘new drugs’ under the FDCA,” within the meaning of “Section

201(g)(1) of the FDCA,” 21 U.S.C. § 321(g)(1). Appx47. The complaint devotes another eight pages to identifying the provisions of the FDCA that govern what constitutes a “drug” and a “new drug,” alleging facts about the articles, and explaining why, in Amarin’s view, the articles qualify as unapproved “new drugs” under the FDCA. Appx47-55. Amarin also identifies warning letters and other statements by FDA regarding what Amarin alleges are similar articles presenting similar violations of the FDCA. Appx37-38, Appx50-51.

Amarin relies on these alleged FDCA violations to establish the central element of Amarin’s false-advertising claim. Appx55-56. The Lanham Act makes it unlawful to use in commercial advertising any “term” that “misrepresents the nature, characteristics, [or] qualities” of goods. 15 U.S.C. § 1125(a)(1)(B). Amarin’s only argument for why the accused articles’ labeling is false or misleading is that it is “literally false” to call the articles “dietary supplements” when they allegedly do not meet the FDCA’s definition of that term and instead are unapproved “new drugs.” Appx55. Amarin provides no reason, other than these alleged FDCA violations, to conclude that the labeling or advertising makes a false or misleading statement. Amarin also relies on these alleged FDCA violations for another element of its false-advertising claim—materiality—alleging that “[i]f consumers knew that the products were illegally marketed unapproved ‘new drugs’ and that, as such, it was unclear whether the products were safe and effective, it would influence the consumers’ purchasing decisions.” *Id.* Amarin’s false-advertising claim, like Amarin’s other claim,

is thus expressly predicated on alleging, proving, and restraining a series of FDCA violations.

It makes no difference that Amarin’s claims require proof of additional matters beyond the alleged violations of the FDCA. To prevail on either of its two claims, for example, Amarin will need to prove that importation of the articles that violate the FDCA will harm Amarin’s business. *See Clock Spring, LP v. Wrapmaster, Inc.*, 560 F.3d 1317, 1329 n.10 (Fed. Cir. 2009) (a false-advertising plaintiff must show that it “has been or is likely to be injured as a result of the [false] statement”); 19 U.S.C. § 1337(a)(1)(A)(i) (a Tariff Act complainant must show a “threat or effect” of “destroy[ing] or substantially injur[ing] an industry in the United States”). But the existence of these additional elements in Amarin’s claims does not change the fact that Amarin’s claim to relief ultimately requires that it prove what are alleged to be violations of the FDCA; nor does it change the fact that Amarin seeks to redress and restrain those FDCA violations. Indeed, Amarin seeks remedies like those that are available to the government—and only to the government—in an FDCA enforcement proceeding. Accordingly, Amarin’s claims are private actions “for the enforcement, or to restrain violations, of” the FDCA, and they are prohibited for that reason. 21 U.S.C. § 337(a).

4. That conclusion is consistent with the consensus of the courts of appeals that have addressed this issue. For example, in *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), a medical-device manufacturer brought a false-advertising claim under

the Lanham Act against a competitor who allegedly advertised its device as “FDA approved” when, the plaintiff contended, the competitor’s device was different enough from a previously-approved device that the competitor was required by the FDCA to make a further filing with FDA, but had not done so. *Id.* at 923-28. The Ninth Circuit held that “[b]ecause the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation.” *Id.* at 924. The court explained that to permit adjudication of the false-advertising claim “would, in effect, permit [the plaintiff] to assume enforcement power which the [FDCA] does not allow and require the finder of fact to make a decision that the FDA itself did not make.” *Id.* at 930.

The Third Circuit reached the same conclusion in *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990), where a drug manufacturer brought a false-advertising claim under the Lanham Act against a competitor, alleging that the labeling on the competitor’s drug lists an ingredient as “inactive” when the FDCA allegedly required that the ingredient be labeled as “active.” *Id.* at 230. The court noted that the plaintiff had provided no reason to think that the labeling was false or misleading other than the contention that the labeling violated the FDCA, and the court noted that FDA had not concluded whether the ingredient at issue was active or inactive or taken enforcement action accordingly. *Id.* at 230-31. The court held that

adjudication of the claim would improperly “usurp” FDA’s exclusive authority, emphasizing that the FDCA does not “create[] an express or implied private right of action,” and concluding that what the FDCA “do[es] not create directly, the Lanham Act does not create indirectly, at least not in cases requiring original interpretation” of the FDCA. *Id.* at 231.

Similarly, in *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), a drug manufacturer brought a false-advertising claim under the Lanham Act against competitors who implicitly represented that their generic drugs were “properly approved by the FDA” by placing those drugs on the market in alleged violation of the FDCA. The Fourth Circuit recognized that a false-advertising claim might proceed if the plaintiff could identify representations in the drug’s packaging or labeling that misled consumers in a way independent of the FDCA. *Id.* But the Fourth Circuit held that “permitting [the plaintiff] to proceed on the theory that the defendants violated [the Lanham Act] merely by placing their drugs on the market would, in effect, permit [the plaintiff] to use the Lanham Act as a vehicle by which to enforce” the FDCA, which, the court noted, the plaintiff “is not empowered” to do. *Id.* This Court quoted this passage with approval in another case, also called *Mylan*, 268 F.3d at 1332, to support this Court’s holding that a claim brought as a declaratory judgment action was actually an improper attempt to enforce the FDCA through a private enforcement proceeding.

Finally, the Second Circuit held in *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997), that an inventor developing a weight-loss product had no standing to bring a false-advertising claim against a competitor under the Lanham Act. In support of that holding, the court concluded that the plaintiff’s “dogged insistence that [the defendant’s] products are sold without proper FDA approval suggests” that the plaintiff’s “true goal is to privately enforce alleged violations of the FDCA,” but “no such private right of action exists.” *Id.*¹

The courts of appeals have applied the same principle consistently in contexts involving other statutory schemes that also prohibit private enforcement actions. For example, in *IQ Products Co. v. Pennzoil Products Co.*, 305 F.3d 368, 374 (5th Cir. 2002), the Fifth Circuit held that the Federal Hazardous Substances Act’s prohibition on private enforcement actions precluded adjudication of a false-advertising claim that was predicated on the allegation that a product’s labeling violated the Act and was false or misleading for that reason. Similarly, in *Dial A Car, Inc. v. Transportation, Inc.*,

¹ *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934 (8th Cir. 2005), is not to the contrary. There, an antibiotic manufacturer brought a false-advertising claim against a competitor whose product was approved by FDA for certain uses but who allegedly falsely advertised additional, unapproved uses. *Id.* at 935-37. The Eighth Circuit held that this claim was cognizable, distinguishing the cases above. It was undisputed in *Alpharma* that the product was a “drug” and that FDA approval was required for each intended use. The court explained that there was thus no need to make a “preemptive determination” about how FDA would categorize the article at issue. *Id.* at 940. The claim rested on whether FDA had approved the competitor’s drug for additional uses —a factual issue that FDA had partially addressed. *Id.* at 939. By contrast, Amarin’s claims rest on disputed allegations about the proper FDCA classification of certain articles, a determination at the heart of FDCA enforcement that FDA has not made.

82 F.3d 484, 489-90 (D.C. Cir. 1996), the D.C. Circuit held that a false-advertising claim was not a proper vehicle by which a taxi company could sue a competitor for advertising itself to be lawfully permitted to operate in the District of Columbia. The Lanham Act could not be used “to interpret and *enforce* municipal regulations” (emphasis in original), at least where the Taxicab Commission had not clearly addressed the issue already. *Id.* at 490; *see also Cottrell, Ltd. v. Biotrol Int’l, Inc.*, 191 F.3d 1248, 1255 (10th Cir. 1999) (holding that plaintiff could not bring a claim seeking enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act “dressed up as a Lanham Act claim”).

B. Amarin’s Arguments Are Without Merit.

1. Amarin chiefly contends that the Supreme Court’s decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), has already settled the question presented in this case. Br. 2, 4, 18, 44-54. But Amarin’s reliance on *POM Wonderful* is fundamentally misplaced.

In *POM Wonderful*, a juice manufacturer brought a false-advertising claim under the Lanham Act against the manufacturer of a competing juice product. 134 S. Ct. at 2233. The plaintiff alleged that the competitor’s labeling misled consumers by prominently featuring the words “pomegranate” and “blueberry” in large type on the product’s label, even though the juice contained only small amounts of each, *id.* at 2233, 2235—allegations entirely independent of the FDCA. Indeed, the plaintiff in *POM Wonderful* did not cite the FDCA, allege that the competitor’s labeling violated

the FDCA, or allege that any such violation was the reason that the labeling was false or misleading. *See* First Am. Compl., *POM Wonderful LLC v. The Coca Cola Co.*, No. 08-cv-6237 (C.D. Cal., filed July 27, 2009) (Dkt. No. 53).

The district court and court of appeals in *POM Wonderful* held that the FDCA nonetheless precluded the plaintiff's false-advertising claim because regulations under the FDCA, which contain detailed provisions governing juice labeling, occupied the field, permitting some features of the defendant's label and prohibiting none of the features alleged to be misleading. 134 S. Ct. at 2236. But the Supreme Court reversed, holding that there was no conflict in fully enforcing both the FDCA and the Lanham Act in that case, where the plaintiff's claims were predicated on statements made on labeling regulated by the FDCA, but were not predicated on proving and remedying violations of the FDCA.

POM Wonderful thus stands for the proposition that the FDCA does not occupy the field of food labeling. False-advertising claims are not precluded by the FDCA simply because the FDCA independently regulates food labeling. As the Court characterized its holding in *POM Wonderful*, "Congress did not intend the FDCA to preclude Lanham Act suits *like POM's.*" 134 S. Ct. at 2241 (emphasis added). And POM, as the Court emphasized, sought "to enforce the Lanham Act, not the FDCA or its regulations." *Id.* at 2239.

POM Wonderful therefore did not decide the question presented here: whether the FDCA’s prohibition on private proceedings to enforce or restrain violations of the FDCA precludes a private party’s claims that seek to prove and stop violations of the FDCA by invoking a private cause of action under another statute. Amarin alleges that the labeling on the accused articles constitutes an “unfair act” under the Tariff Act, and “false” advertising under the Lanham Act, solely *because* the articles allegedly violate the FDCA’s requirements. Amarin’s claims thus come into direct conflict with the government’s exclusive enforcement authority under the FDCA. And *POM Wonderful* expressly left open the question whether the FDCA precludes private causes of action brought under other statutes where those statutes and the FDCA “cannot be implemented in full at the same time.” 134 S. Ct. at 2240.

In the wake of *POM Wonderful*, courts have recognized this distinction between false-advertising claims that rest on FDCA violations and those that do not. Courts have permitted adjudication of false-advertising claims involving allegations not predicated on proving FDCA violations, like claims that a dietary supplement was falsely advertised as “safe” and “natural” when it was neither, under the common meaning of those words. *See ThermoLife Int’l, LLC v. Gaspari Nutrition Inc.*, 648 F. App’x 609, 612 (9th Cir. 2016) (unpublished). But they have properly continued to hold that Lanham Act claims predicated on proving and restraining FDCA violations are precluded, consistent with the consensus among the courts of appeals on that

issue before POM *Wonderful*. See, e.g., *Hi-Tech Pharm., Inc. v. Hedges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1331 (N.D. Ga. 2016); Appellee Br. 24-25 (collecting cases).

2. Taking a different tack, Amarin argues (Br. 54-56) that the Commission’s conclusion that the FDCA precludes Amarin’s claims “cannot be reconciled” with this Court’s opinion in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013). But *Allergan* is fully consistent with the Commission’s conclusion.

The plaintiff in *Allergan* sold an eyelash-growth product and sued a competitor for alleged violations of California’s Sherman Food, Drug, and Cosmetic Law, *see Cal. Health & Safety Code § 109875 et seq.*, which parallels the FDCA. The plaintiff alleged that the competitor was wrongly marketing an eyelash-growth product as a “cosmetic” when it was actually an unapproved “new drug,” under California law. *Allergan*, 738 F.3d at 1353. The plaintiff brought the action under California’s Unfair Competition Law, which creates a cause of action to remedy violations of state business laws like the Sherman Law. Cal. Bus. & Prof. Code § 17203.

This Court held in *Allergan* that the FDCA did not impliedly preempt the plaintiff’s state-law claim. 738 F.3d at 1355. The Court reasoned that California’s Sherman Law regulated in areas—health and safety—that “implicate an historic state power that may be vindicated under state law tort principles” absent a “clear and manifest purpose of Congress” to preempt such state law. *Id.* Applying this presumption against preemption, the Court “d[id] not find a clear purpose by Congress to preempt the state law claim at issue.” *Id.* And the Court concluded that

the Sherman Law “is not an obstacle to realizing federal goals” because “it contains provisions that parallel the FDCA, such that the statutes have consistent goals.” *Id.* at 1355-56. The Court distinguished *Buckman*, 531 U.S. 341, which held that the FDCA preempted a state tort claim predicated on alleged fraud against FDA. The *Allergan* Court reasoned that the tort action in *Buckman* “existed—unlike [the *Allergan* plaintiff’s] claim—‘solely by virtue of the FDCA disclosure requirements.’” 738 F.3d at 1356 (quoting *Buckman*, 531 U.S. at 352-53). The claim in *Allergan* existed solely by virtue of independent state law.

Allergan does not support Amarin’s argument that private parties may use the Tariff Act to enforce or restrain violations of the FDCA. The *Allergan* claim did not run afoul of the FDCA’s prohibition on private enforcement proceedings because the claim did not attempt to enforce the FDCA. Rather, the claim sought to enforce compliance with an independent state statute—the Sherman Law—using a state cause of action that permits private enforcement of the Sherman Law. To be sure, the contents of the Sherman Law paralleled the FDCA. But the Sherman Law was not dependent on the FDCA for its existence. And it was this independent state law, not the FDCA, that the *Allergan* plaintiff sought to enforce in a private action for unfair competition under state law.

Amarin, by contrast, seeks to prove and remedy violations of the FDCA itself through the claims brought under the Tariff Act, and the FDCA prohibits such private enforcement proceedings. *Accord* U.S. Amicus Br., *Athena Cosmetics, Inc. v.*

Allergan, Inc., No. 13-1379, 2015 WL 2457643, at *18 (U.S. May 26, 2015) (distinguishing *Allergan* from cases, like *PDK Labs*, that are “essentially efforts to enforce the FDCA itself, rather than parallel state law”); U.S. Amicus Br., *Albertson’s, Inc. v. Kanter*, No. 07-1327, 2008 WL 5151069, at *8 (U.S. Dec. 5, 2008) (“Although 21 U.S.C. 337 precludes private actions to enforce the FDCA itself, Section 337 does not prohibit private actions to enforce parallel state requirements.”).

That distinction—between suits to enforce the independent Sherman Law and impermissible suits to enforce the FDCA—is bolstered by the federalism interests at issue in *Allergan*, which are absent here. This Court noted in *Allergan* that California’s Sherman Law was enacted pursuant to the state’s “historic police powers,” and the Court therefore applied a presumption against preemption, which, it held, the FDCA did not overcome. 738 F.3d at 1355; *accord* U.S. Amicus Br., *Athena*, 2015 WL 2457643, at *11-17 (relying on the presumption against preemption). In so holding, this Court left for state law the interpretation and enforcement of state law within California. And it did so secure in the knowledge that private actions under state law to enforce state law would have no necessary consequence for the proper interpretation and enforcement of the FDCA itself.

Not so, here. Amarin’s claims seek to enforce and restrain violations of the FDCA—a federal statute. Adjudication of those claims would directly enforce the FDCA, with nationwide effect. Worse, nothing in Amarin’s theory would seem to prevent other private commercial competitors from bringing claims under the

Lanham Act in federal courts across the country seeking to prove and remedy alleged FDCA violations, with potentially precedential effect. That would effectively circumvent FDA's exclusive control over how products are regulated under the FDCA and which products warrant enforcement proceedings. And it would significantly diminish the benefits that Congress secured in centralizing "all" decisions to bring FDCA enforcement proceedings. 21 U.S.C. § 337(a). As discussed above, Amarin's claims are precluded by the FDCA under the normal tools of statutory construction. And, unlike in *Allergan*, there is no extra thumb on the scale in analyzing that question—no presumption against preemption to protect independent state law—because there are no federalism interests at stake. *See* 738 F.3d at 1356 (applying the presumption against preemption and distinguishing preclusion cases like *PhotoMedex*).

3. Finally, Amarin appears to argue (Br. 5, 18, 51, 63) that two provisions of the Tariff Act override the FDCA's express prohibition on private enforcement proceedings. Amarin notes that the Commission's remedies are "in addition to any other provision of law," 19 U.S.C. § 1337(a)(1), and that the Tariff Act generally requires that other parts of the Executive Branch "shall cooperate fully" with the Commission "for the purposes of aiding and assisting its work," *id.* § 1334.

Neither provision qualifies the FDCA's flat prohibition on "all" private proceedings "for the enforcement, or to restrain violations, of" the FDCA. 21 U.S.C. § 337(a). The "in addition" provision does not address when a complainant's claim is

cognizable (the question here); it conditionally indicates that “when” the Commission finds an “unfair act” in a claim properly before it, the Tariff Act’s remedies shall be “in addition” to any others. 19 U.S.C. § 1337(a)(1). Moreover, the “in addition” provision preserves other remedies—an issue unrelated to whether the later-enacted *FDCA* displaces an application of the *Tariff Act* that is incompatible with the FDCA’s specific prohibition on private enforcement proceedings. The “shall cooperate” provision speaks to how agencies assist the Commission where the Commission has jurisdiction. It does not blithely require all other federal agencies to make regulatory enforcement determinations that are exclusively reserved to those agencies in their organic acts, much less override the clear language of 21 U.S.C. § 337(a).

CONCLUSION

For the foregoing reasons, this Court should hold that the FDCA precludes Amarin's claims.

Respectfully submitted,

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March 2018

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rules of Appellate Procedure 29 and 32(a). This brief was prepared using Microsoft Word 2013 in Garamond 14-point font, a proportionally spaced typeface. This brief contains 6,995 words.

/s/ Joseph F. Busa

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CERTIFICATE OF SERVICE

I hereby certify that on March 27, 2018, I electronically filed the foregoing corrected brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Joseph F. Busa

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TAB 3

2019 WL 5784708 (U.S.) (Appellate Petition, Motion and Filing)
Supreme Court of the United States.

AMARIN PHARMA, INC., et al., Petitioners,

v.

INTERNATIONAL TRADE COMMISSION, et al.

No. 19-152.

November 4, 2019.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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***I QUESTION PRESENTED**

Whether a private party's claim under the Lanham Act, [15 U.S.C. 1051 et seq.](#), presented in a complaint seeking an unfair-trade-practices investigation by the United States International Trade Commission under [19 U.S.C. 1337](#), is cognizable when that claim is based solely on an alleged violation of the new-drug provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), [21 U.S.C. 301 et seq.](#), and the Food and Drug Administration has not determined that the FDCA has been violated.

***II ADDITIONAL RELATED PROCEEDING**

United States Court of Appeals (Fed. Cir.):

Amarin Pharma, Inc. v. International Trade Comm'n (In re Amarin Pharma, Inc.), No. 18-114 (May 1, 2019)

***III TABLE OF CONTENTS**

Opinions below	1
Jurisdiction	1
Statement	1
Argument	10
Conclusion	22

TABLE OF AUTHORITIES

Cases:

<i>Buckman Co. v. Plaintiffs' Legal Comm.</i> , 531 U.S. 341 (2001)	4, 12
<i>Cheney v. United States Dist. Court</i> , 542 U.S. 367 (2004)	11, 21, 22
<i>Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH</i> , 843 F.3d 48 (2d Cir. 2016)	10, 16
<i>Heckler v. Chaney</i> , 470 U.S. 821 (1985)	20
<i>Izumi Seimitsu Kogyo Kabushiki Kaisha v. United States</i>	18
<i>Philips Corp.</i> , 510 U.S. 27 (1993)	
<i>POM Wonderful LLC v. Coca-Cola Co.</i> , 573 U.S. 102 (2014)	4, 9, 10, 13, 14
<i>Textron, Inc. v. U.S. Int'l Trade Comm'n</i> , 753 F.2d 1019 (Fed. Cir. 1985)	3
<i>Wood v. Allen</i> , 558 U.S. 290 (2010)	18
Statutes and regulations:	
Administrative Procedure Act, 5 U.S.C. 701 <i>et seq.</i>	19
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 <i>et seq</i>	3
21 U.S.C. 321	15
21 U.S.C. 321(g)(1)	3, 5, 15
21 U.S.C. 321(p)	3, 15
*IV 21 U.S.C. 321(ff)	3, 5, 15
21 U.S.C. 321(ff)(3)(A)	3
21 U.S.C. 331(b)	3
21 U.S.C. 337(a)	4, 7, 11, 12, 15, 17
21 U.S.C. 337(b)	4, 14
21 U.S.C. 352(a) (Supp. IV 2016)	3, 5
21 U.S.C. 352(n)	5
21 U.S.C. 355(a)	3, 5
Tariff Act of 1930, as amended, 19 U.S.C. 1202 <i>et seq</i>	1
19 U.S.C. 1330(d)(5)	2, 18
19 U.S.C. 1333(g)	7
19 U.S.C. 1334	15
19 U.S.C. 1337	passim
19 U.S.C. 1337(a)	16
19 U.S.C. 1337(a)(1)	2, 16
19 U.S.C. 1337(a)(1)(A)	1, 2, 11
19 U.S.C. 1337(b)	8, 19
19 U.S.C. 1337(b)(1)	2, 8, 17, 19, 20
19 U.S.C. 1337(c)	2, 10, 11, 18, 19, 20
19 U.S.C. 1337(d)	19, 20
19 U.S.C. 1337(d)-(g)	19
19 U.S.C. 1337(d)(1)	2, 18, 20
19 U.S.C. 1337(e)	19, 20
19 U.S.C. 1337(e)(1)	2, 18, 20
19 U.S.C. 1337(f)	19
19 U.S.C. 1337(f)(1)	2, 18, 20
19 U.S.C. 1337(g)	19
19 U.S.C. 1337(g)(1)	2, 18
19 U.S.C. 1337(g)(1)(B)	20
19 U.S.C. 1337(j)(1)(B)	20
19 U.S.C. 1337(j)(2)	18, 20
*V 19 U.S.C. 1337(j)(4)	20
Trademark Act of 1946, ch. 540, 60 Stat. 427 (15 U.S.C. 1051 <i>et seq.</i>)	3
15 U.S.C. 1125(a)(1)(B)	2, 3, 11
28 U.S.C. 1295(a)(6)	2, 8, 10, 11, 18, 19
19 C.F.R.:	
Section 210.9(a)	2

Section 210.10(a)(1)

2

*1 OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-38) is reported at [923 F.3d 959](#). The decision of the United States International Trade Commission (Pet. App. 39-42) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 1, 2019. The petition for a writ of certiorari was filed on July 30, 2019. The jurisdiction of this Court is invoked under [28 U.S.C. 1254\(1\)](#).

STATEMENT

1. a. The Tariff Act of 1930, as amended, [19 U.S.C. 1202 et seq.](#), prohibits certain “[u]nfair methods of competition and unfair acts in the importation of articles *** into the United States, or in the sale of such articles by the owner, importer, or consignee.” [19 U.S.C. 1337\(a\)\(1\)\(A\)](#). Congress has directed the United States [*2](#) International Trade Commission (Commission) to “investigate any alleged violation of [Section 1337] on complaint under oath or upon its initiative,” [19 U.S.C. 1337\(b\)\(1\)](#), if “one-half of the number of commissioners voting agree that the investigation should be made,” [19 U.S.C. 1330\(d\)\(5\)](#). See [19 C.F.R. 210.9\(a\), 210.10\(a\)\(1\)](#). Once “an investigation is initiated,” the Commission must set a target date for the agency’s “final determination.” [19 U.S.C. 1337\(b\)\(1\)](#).

After completing its investigation, the Commission “shall determine *** whether or not there is a violation of [Section 1337]” unless the matter is resolved by a consent order or agreement between the private parties. [19 U.S.C. 1337\(c\)](#). If the Commission finds such a violation, the violation “shall be dealt with, in addition to any other provision of law, as provided in [Section 1337].” [19 U.S.C. 1337\(a\)\(1\)](#); see [19 U.S.C. 1337\(c\)](#). [Section 1337](#) authorizes the Commission to exclude the offending articles “from entry into the United States” and/or to issue a cease-and-desist order, unless the Commission finds that the “effect of such” exclusion or order on certain public interests warrants a different course. [19 U.S.C. 1337\(d\)\(1\), \(e\)\(1\), \(f\)\(1\) and \(g\)\(1\)](#). “Any person adversely affected by a final determination of the Commission under [Section 1337](d), (e), (f), or (g)” may obtain judicial review in the Federal Circuit, [19 U.S.C. 1337\(c\)](#), which possesses corresponding jurisdiction to review “the final determinations of the [Commission] relating to unfair practices in import trade, made under section [1]337,” [28 U.S.C. 1295\(a\)\(6\)](#).

b. The Commission has long understood the “[u]nfair methods of competition and unfair acts” prohibited by [Section 1337](#), [19 U.S.C. 1337\(a\)\(1\)\(A\)](#), to include the importation of articles that violate [15 U.S.C. 1125\(a\)\(1\)\(B\)](#), [*3](#) a provision of the Trademark Act of 1946 (Lanham Act), ch. 540, 60 Stat. 427 ([15 U.S.C. 1051 et seq.](#)). [Section 1125\(a\)\(1\)\(B\)](#) makes it unlawful for any person to “use[] in commerce any word, term, name, symbol, or device, or any combination thereof” that “in commercial advertising or promotion, misrepresents the nature, characteristics, [or] qualities *** of his or her or another person's goods.” [15 U.S.C. 1125\(a\)\(1\)\(B\)](#); see, e.g., *Textron, Inc. v. U.S. Int'l Trade Comm'n*, 753 F.2d 1019, 1023 (Fed. Cir. 1985). The Commission therefore may investigate, as a possible violation of [Section 1337](#), an allegation of false or misleading representations involving imported articles.

This case concerns the intersection between (1) the Commission's general authority to investigate such Lanham Act violations under [Section 1337](#) and (2) the authority of the Food and Drug Administration (FDA), acting through the United States, to enforce the Federal Food, Drug, and Cosmetic Act (FDCA), [21 U.S.C. 301 et seq.](#) As relevant here, the FDCA generally prohibits any person from introducing, or delivering for introduction, into interstate commerce any “new drug,” unless an FDA-approved application for that drug is effective. [21 U.S.C. 355\(a\)](#); see [21 U.S.C. 321\(g\)\(1\)](#) and [\(p\)](#) (defining “drug” and “new drug”). Cf. [21 U.S.C. 321\(ff\)](#) and [\(3\)\(A\)](#) (defining “dietary supplement,” which generally is “deemed to be a food” under the

FDCA, to “include an article that is approved as a new drug” in certain contexts). The FDCA also prohibits the “misbranding” of a drug through the use of false or misleading labeling. [21 U.S.C. 331\(b\)](#); [21 U.S.C. 352\(a\)](#) (Supp. IV 2016).

The United States has exclusive authority to bring enforcement actions for violations of the FDCA's new-drug provisions. “Except as provided in [Section 337](b)” - *4 which authorizes a State to enforce FDCA provisions governing adulterated food within that State - “all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.” [21 U.S.C. 337\(a\)](#); see [21 U.S.C. 337\(b\)](#). [Section 337\(a\)](#) thus “leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA's] provisions.” *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001); see *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102,109 (2014) (“Private parties may not bring [FDCA] enforcement suits.”).

2. a. Petitioners market Vascepa, an FDA-approved drug that contains eicosapentaenoic acid, a type of [Omega-3 fatty acid](#) commonly known as EPA. Pet. App. 4. This case concerns petitioners' complaint (*id.* at 96-229) asking the Commission to “commence an investigation into the [allegedly] unlawful importation or sale” of “synthetically produced” Omega-3 fish oil products. *Id.* at 105. The complaint alleges that such Omega-3 products are “falsely labeled, and/or promoted for use as, or in[,] ‘dietary supplements.’” *Ibid.* (citation omitted). Such labeling and promotion, the complaint contends, constitute “an unfair act and/or unfair method of competition under Section [1]337,” because the Omega-3 products so marketed are not “b1 ‘dietary supplements’ but [rather] are actually unapproved ‘new drugs’ under the [FDCA].” *Ibid.*; see *id.* at 106 (stating that other Omega-3 products “comprised of common fish oil” are “not synthetically produced” and are permissibly marketed as “dietary supplements”).

The complaint asserts two related claims for investigation. Petitioners' primary claim is that the labeling and promotion of the Omega-3 products as “dietary *5 supplements” violate the Lanham Act and, hence, [Section 1337](#). Pet. App. 130-161. The complaint recognizes that a Lanham Act claim requires “a false or misleading statement of fact” about a product. *Id.* at 131. It alleges that the “[l]abeling and/or promoti[on]” of the Omega-3 products for use in, or as, “ ‘dietary supplements’” was “literally false,” because such products “cannot meet the definition of ‘dietary supplement’ in Section 201(ff) of the FDCA, [21 U.S.C. § 321\(ff\)](#),” and “are actually unapproved ‘new drugs’” under the FDCA. *Id.* at 133-134; see *id.* at 134-150 (arguing that the products do not satisfy [Section 321\(ff\)](#)'s requirements for “dietary supplements”); *id.* at 151-159 (arguing that the products are “drugs” under [21 U.S.C. 321\(g\)\(1\)](#) and are unapproved “new drugs”).

Petitioners' secondary claim is that the importation and sale of synthetically produced Omega-3 products “constitute unfair acts or unfair methods of competition under Section [1]337 based upon the standards set forth in the FDCA.” Pet. App. 161; see *id.* at 161-165. The complaint argues that the FDCA prohibits the “introduction *** into interstate commerce of any unapproved ‘new drug,’” and that the introduction of the private respondents' products into interstate commerce “violates the standards set forth in Section 505(a) of the FDCA, [21 U.S.C. 355(a)],” because their products “are actually unapproved ‘new drugs.’” *Id.* at 161. The complaint further alleges the private respondents' conduct violates other FDCA provisions as well. *Id.* at 162-165; see, e.g., *id.* at 162 (asserting violation of the FDCA's prohibition against false or misleading statements in labeling and promotional materials for drugs, [21 U.S.C. 352\(a\)](#) (Supp. IV 2016) and (n), because describing the Omega-3 products as “ ‘dietary supplements’” is allegedly “false[]”).

*6 b. While petitioners' investigation request was pending, FDA submitted to the Commission a letter (Pet. App. 232-245) “request[ing] that the Commission decline to initiate the requested investigation,” *id.* at 244. FDA stated that “Congress has authorized only FDA to initiate FDCA enforcement actions.” *Id.* at 233. FDA also stated that, under the FDCA's “complex statutory scheme, determinations of whether a product is a dietary supplement require case-specific analysis,” and that “very small differences in factors such as an ingredient's chemical structure or history of presence in the food supply can mean the difference between dietary-ingredient status and non-dietary-ingredient status.” *Id.* at 235. FDA further stated that it was “in the process of developing a guidance document for industry on when a dietary supplement ingredient is [a new dietary ingredient]” that requires pre-marketing regulatory compliance, *id.* at 235-236, and was contemplating the development of “an authoritative list of pre-October 15, 1994, dietary ingredients [exempt from that requirement] based on independent and verifiable data,”

id. at 237. FDA cautioned that a “Commission finding on issues raised in [petitioners’] Complaint here could conflict” with such FDA guidance. *Ibid.*

c. The Commission declined to institute an investigation and dismissed petitioners’ complaint. Pet. App. 39-42. The agency determined that petitioners’ “complaint does not allege an unfair method of competition or an unfair act” that is “cognizable” under [Section 1337](#). *Id.* at 40. The Commission stated that “the Lanham Act allegations in this case are precluded by the [FDCA],” which “the [FDA] is charged with *** administ[ering].” *Ibid.*

*7 3. Petitioners filed a petition for review and a separate mandamus petition in the court of appeals, which the court consolidated for its review. Pet. App. 5.

The Commission, as respondent, defended its decision not to institute an investigation. The Commission explained that “[petitioners’] claims are entirely predicated on a violation of the FDCA”; that “Congress [has] expressly and exclusively assigned to the FDA” the authority to “interpret[] and appl[y]” the FDCA “in the first instance”; and that, “[w]ithout sufficient guidance from the FDA,” petitioners’ claims before the Commission were not cognizable. Commission C.A. Br. 16-17, 20. The Commission stated that petitioners would later be “free to file a new complaint” if “FDA issues sufficient guidance with respect to the accused products such that the Commission is not required to interpret the FDCA in the first instance and [petitioners’] claims are otherwise no longer precluded by the FDCA.” *Id.* at 58. ¹

¹ In the court of appeals, the Commission appeared through its own attorneys as authorized by [19 U.S.C. 1333\(g\)](#).

The United States, as amicus curiae, argued that the United States’ exclusive authority to “enforce[], or to restrain violations, of [the FDCA],” [21 U.S.C. 337\(a\)](#), precludes private parties from asserting a claim nominally based on another statute if, “as a necessary element” of that claim, the party must establish (and thus seek redress for) a “violation[] of the FDCA itself.” U.S. Corrected C.A. Amicus Br. 7-8.

4. The court of appeals denied petitioners’ petition for review and petition for mandamus. Pet. App. 1-38.

a. i. The court of appeals held that it possessed jurisdiction to review the Commission’s decision not to institute a [Section 1337\(b\)](#) investigation. Pet. App. 6-11. *8 The court stated that its statutory jurisdiction to review “final determinations of the [Commission] relating to unfair practices in import trade, made under section [1]337,” [28 U.S.C. 1295\(a\)\(6\)](#), requires a “final determination decision *on the merits*.” Pet. App. 6-7 (citation omitted). The court concluded, however, that the Commission’s decision not to investigate here was “‘intrinsically’” a “‘determination *on the merits*’” because that decision reflected the agency’s view that petitioners’ claims “were precluded by the FDCA.” *Id.* at 8 (citation omitted).

ii. Petitioners contended that the Tariff Act imposes a “mandatory duty to institute an investigation in this case” by directing that the Commission “‘shall investigate any alleged violation of [Section 1337].’” Pet. App. 11 (quoting [19 U.S.C. 1337\(b\)\(1\)](#)). The court of appeals rejected that argument. *Id.* at 11-13. It read the Tariff Act to provide that “the Commission may decline to institute an investigation where a complaint fails to state a cognizable claim under [Section] [1]337.” *Id.* at 13.

iii. The court of appeals upheld the Commission’s determination that petitioners’ [Section 1337](#) claims were not cognizable because the FDCA precludes those claims. Pet. App. 13-21. The court thus denied petitioners’ petition for review, *id.* at 22, and, to the extent petitioners continued to seek mandamus, denied mandamus relief, *id.* at 11 n.3, 22.

The court of appeals held that petitioners’ [Section 1337](#) claims ultimately rest on alleged “violations of the FDCA.” Pet. App. 16-17. The court reasoned that petitioners’ Lanham Act claim alleging false or misleading marketing of “products as ‘dietary supplements,’” when the products allegedly are “‘unapproved ‘new drugs’ under the FDCA,’ b1” necessarily requires “proving violations *9 of the FDCA.” *Ibid.* (quoting petitioners’ complaint). “Every allegation” supporting petitioners’ separate unfair-competition claim “based on the standards set forth in the FDCA” similarly “rests on an alleged violation of the FDCA.” *Id.* at

17. The court further observed that “FDA has not provided guidance as to whether the products at issue in this case should be considered ‘new drugs’ that require approval.” *Id.* at 1819. The court concluded that “a complainant fails to state a cognizable claim under [Section] [1]337 where that claim is based on proving violations of the FDCA and where the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA.” *Id.* at 19.

The court of appeals explained that its holding was consistent with *POM Wonderful*, *supra*. Pet. App. 19-20. The court observed that *POM Wonderful* did not involve a Lanham Act claim that “require[d] proving a violation of the FDCA.” *Id.* at 20. The court viewed this Court’s decision as holding only that regulation of a particular product under the FDCA does “not categorically preclude a Lanham Act claim based on [that] product.” *Ibid.* The court explained that *POM Wonderful* does not address the distinct question whether a claim “based solely on alleged violations of the FDCA’s requirements” would be precluded. *Ibid.*

The court of appeals observed that its “limited holding” concerning [Section 1337](#) claims based solely on violations of the FDCA, in circumstances where FDA has not provided guidance about the status of disputed products, was “consistent with the Commission’s arguments” that such “claims are precluded *at least* until the FDA has provided guidance as to whether the products at issue are dietary supplements.” Pet. App. 19. The [*10](#) court stated that, although “the United States, as amicus, appears to seek a broader ruling - that all such claims are precluded *regardless* of whether the FDA has provided guidance” - the court did “not [need to] address that broader question here,” because no relevant FDA guidance yet exists. *Ibid.*

b. Judge Wallach dissented. Pet. App. 22-38. Although he “agree[d] with the majority’s conclusion that the [Commission] did not err in declining to institute an investigation,” he would have ruled for the Commission under a different jurisdictional “approach.” *Id.* at 23. Judge Wallach would have held that the court of appeals lacked jurisdiction over the petition for review because the Commission’s decision not to investigate is not a “final determination” reviewable under [19 U.S.C. 1337\(c\)](#) and [28 U.S.C. 1295\(a\)\(6\)](#). Pet. App. 22-35. Judge Wallach concluded that the court instead possessed only mandamus jurisdiction, and he “agree[d] with the majority’s conclusion that [petitioners] ha[ve] failed to demonstrate that [they are] entitled to the extraordinary relief of mandamus.” *Id.* at 35, 37; see *id.* at 23, 35-37.

ARGUMENT

Petitioners challenge the court of appeals’ holding that the FDCA precludes their Lanham Act claim. Pet. 22-28. Petitioners further contend that the decision below conflicts with this Court’s decision in *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014), see Pet. 22-25, and with the Second Circuit’s application of *POM Wonderful* in *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48 (2016), see Pet. 28-33. The decision of the court of appeals is correct, does not conflict with *POM Wonderful* or *Church & Dwight Co.*, and does not independently warrant [*11](#) review absent a relevant conflict of authority. Furthermore, this case would be a poor vehicle for review, because the court of appeals lacked jurisdiction under [19 U.S.C. 1337\(c\)](#) and [28 U.S.C. 1295\(a\)\(6\)](#) to review the Commission’s refusal to institute an investigation. Although the court of appeals did possess mandamus jurisdiction, petitioners do not present their arguments through the limited lens of mandamus, which requires a “clear and indisputable” right to relief, *Cheney v. United States Dist. Court*, 542 U.S. 367, 381 (2004) (citation omitted).

1. Petitioners’ [Section 1337](#) claims are “based entirely on - and could not exist without - the FDCA,” because each “rests on an alleged violation of the FDCA” and “requires proving violations of the FDCA.” Pet. App. 17-18. The court of appeals correctly held that those claims were not cognizable under [Section 1337](#) because the FDCA “preclude[s]” private enforcement through such purely derivative claims, at least where “FDA has not taken the position that the articles at issue do, indeed, violate the FDCA.” *Id.* at 19; see *id.* at 14 (citing [21 U.S.C. 337\(a\)](#)).

a. Petitioners do not dispute that their [Section 1337](#) claims are ultimately premised on allegations that the FDCA was violated. As construed by the Commission, [Section 1337](#)’s ban on “[u]nfair methods of competition and unfair acts in the importation of articles *** into the United States” that threaten certain adverse effects on industry or commerce, [19 U.S.C. 1337\(a\)\(1\)\(A\)](#), includes Lanham Act violations involving the use in commercial advertising or promotion of a word or term that “misrepresents

the nature, characteristics, [or] qualities" of relevant goods, 15 U.S.C. 1125(a)(1)(B). See *12 pp. 2-3, *supra*. The Lanham Act misrepresentation alleged here is the purported mislabeling as "dietary supplements" of certain products that petitioners assert "are actually unapproved 'new drugs'" under the FDCA. Pet. App. 134, 156-160; see pp. 4-5, *supra*.

Subject to an exception that is not implicated here, however, "all *** proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. 337(a). That provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA's] provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001). Section 337(a) thus precludes a private party from pursuing a claim that requires proof of a "violation of FDCA requirements" and thus exists "solely by virtue of the FDCA." *Id.* at 352-353. Allowing private litigants to bring claims that are purely derivative of FDCA requirements would displace the complex scientific and administrative judgments that actions to restrain FDCA violations require, and that Congress has vested exclusively in an expert federal agency (*i.e.*, FDA) exercising its authority through the United States.

The court of appeals thus correctly held that, at least if FDA has not already determined that an FDCA violation has occurred, a derivative Section 1337 claim "based entirely" on an alleged FDCA violation is precluded. Pet. App. 18-19. The court emphasized that its "limited holding" did not resolve whether such a claim would continue to be precluded even after FDA has made that determination, because that "broader question" was not presented in this case. *Id.* at 19.

*13 b. Petitioners do not squarely join issue with the court of appeals' rationale. Instead, they argue that the court's decision "conflicts with *POM Wonderful*," Pet. 22-25, and fails to account for the Commission's independent unfair-trade-practices authority under Section 1337, Pet. 26-28. Petitioners are wrong.

i. *POM Wonderful* did not involve a Lanham Act claim that was purely derivative of the FDCA. *POM Wonderful* instead addressed whether the FDCA precluded a traditional Lanham Act claim alleging that "misleading product descriptions" on beverage labeling had caused consumer "confusion" diminishing POM's beverage sales. *POM Wonderful*, 573 U.S. at 106, 110. That claim did not depend on any showing that the labeling violated the FDCA. See *ibid.*; *id.* at 118-119 (name of juice blend was affirmatively authorized by FDA). The Court's conclusion that "Congress did not intend the FDCA to preclude Lanham Act suits like POM's," *id.* at 121; see *id.* at 106 (addressing "suits like the one brought by POM"), thus does not speak to claims like petitioners'.

Central to the Court's decision was its conclusion that the FDCA and the Lanham Act are designed to "complement each other with respect to food and beverage labeling," so that "the FDCA and its regulations are *** [not] a ceiling on the regulation of [that] labeling." *POM Wonderful*, 573 U.S. at 119; see *id.* at 106, 115, 118. The Court explained that "Lanham Act suits draw upon th[e] market expertise" of competitors that "manufacture or distribute products," that have "detailed knowledge regarding how consumers rely upon certain sales and marketing strategies," and whose "awareness of unfair competition practices may be far more *14 *** accurate than that of agency rulemakers and regulators." *Id.* at 115 (citation omitted). The Court acknowledged that Congress intended FDA to be responsible for actions based on "the FDCA and the detailed prescriptions of its implementing regulations." *Ibid.*; see *id.* at 109 ("Private parties may not bring [FDCA] enforcement suits."); cf. 21 U.S.C. 337(b) (vesting States with some authority over adulterated food). But the Court viewed FDA's technical expertise and authority over the FDCA in the food context as addressing considerations different from those relevant to the typical Lanham Act claim before it, because FDA does not have "the same perspective or expertise in assessing market dynamics that day-to-day competitors possess." 573 U.S. at 115; cf. *id.* at 109 (noting "the less extensive role the FDA plays in the regulation of food than in the regulation of drugs").

In this case, by contrast, the court of appeals did not rely on the mere existence of FDCA regulation to preclude petitioners' claim. Unlike the claims in *POM Wonderful*, petitioners' Lanham Act claim is wholly derivative of the FDCA's distinct requirements for "drugs" and "dietary supplements" and ultimately "requires proving violations of the FDCA." Pet. App. 17-18. Rather than draw upon the Lanham Act's "complement[ary]" regulatory provisions that "impose 'different requirements and protections,' " *POM Wonderful*, 573 U.S. at 115 (citation omitted), petitioners seek to restrain a violation of the FDCA itself. See Pet. App.

20 (concluding that petitioners' claim "stands in stark contrast to" the "Lanham Act claim in *POM Wonderful*," which "did not require proving a violation of the FDCA").

ii. Petitioners argue (Pet. 26-28) that their complaint to the Commission sought to assert "separate rights" *15 under [Section 1337](#) and did not seek "remedies under the FDCA." They acknowledge, however, that "the unfair trade practices" that they challenge "reflect violations of the FDCA," Pet. 27, and they do not assert any [Section 1337](#) claim that could be proved *without* establishing an FDCA violation.

Petitioners appear to suggest that their Lanham Act claim is a freestanding claim because it relies on the Lanham Act's independent prohibition against the misleading use of terms in commercial labeling. But the only basis for their misleading-labeling claim is that the Omega-3 fish oil labeling at issue is inconsistent with the FDCA's definitions of "drug," "new drug," and "dietary supplement," [21 U.S.C. 321\(g\)\(1\), \(p\), and \(ff\)](#). See Pet. App. 113, 133-141, 151-159 (complaint relying on those definitions). Like all of the definitions in [Section 321](#), those definitions apply only "[f]or the purposes of [the FDCA]." [21 U.S.C. 321](#). Because petitioners assert a wholly derivative claim that relies solely upon alleged violations of the FDCA, in a circumstance where FDA has not found any such violation, their claim impermissibly intrudes on FDA's exclusive authority to "restrain [FDCA] violations." [21 U.S.C. 337\(a\)](#).

iii. Petitioners suggest (Pet. 20) that the court of appeals' analysis "overlooks key provisions in the Tariff Act that are designed to prevent any intrusion on FDA's proper prerogatives." The provisions petitioners invoke (Pet. 21) are inapposite.

One such provision states that the Commission shall "in appropriate matters" act in "cooperation" with other federal agencies, which "shall cooperate fully with the commission for the purposes of aiding and assisting in its work." [19 U.S.C. 1334](#). That textual reference to "appropriate matters" involving the "[Commission]'s *16 work" is fully consistent with the court of appeals' determination that petitioners cannot bring to the Commission matters that the FDCA reserves for FDA. [Section 1337\(a\)](#) is similarly unhelpful to petitioners' argument. It states that unlawful acts violating that provision, "when found by the Commission to exist[,] shall be dealt with, in addition to any other provision of law, as provided in [Section 1337]." [19 U.S.C. 1337\(a\)\(1\)](#). That provision makes clear that the exclusion and cease-and-desist orders specified in [Section 1337](#) supplement other statutory remedies *if* the Commission has found a violation. It does not define the circumstances in which the Commission must or should determine whether a violation has occurred.

2. a. Petitioners contend (Pet. 28-30) that the decision below conflicts with the Second Circuit's decision in *Church & Dwight Co., supra*. Petitioners' reliance on *Church & Dwight Co.* is misplaced.

Church & Dwight Co. involved a Lanham Act claim that, like the claim in *POM Wonderful*, did not depend on proof of an FDCA violation. The false-advertising claim in *Church & Dwight Co.* alleged that the defendant's pregnancy test, which was the first to estimate the number of weeks that its user had been pregnant, was misleading because it communicated the number of weeks since a woman's ovulation, rather than the more standard estimate of the number of weeks "since the woman's last menstrual period." [843 F.3d at 53](#). Although FDA had determined that the product's labeling satisfied FDCA requirements, the court held that the Lanham Act challenge could go forward because the FDCA's labeling requirements did not displace the Lanham Act's distinct provisions governing "the capacity of the representations to mislead." *Id. at 63*. The *17 plaintiff therefore could attempt to prove its claim without impinging on FDA's exclusive authority "to restrain [FDCA] violations." [21 U.S.C. 337\(a\)](#). Thus, like this Court in *POM Wonderful*, the Second Circuit had no occasion to address the distinct situation presented here, where a plaintiff presents a Lanham Act claim that is wholly derivative of an alleged FDCA violation.

b. Petitioners also contend (Pet. 20-21) that review is warranted because "[t]he Federal Circuit is the only court with direct appellate jurisdiction over final decisions and determinations by the Commission," such that "no further caselaw development is likely to occur," Pet. 20. But questions concerning the interplay between the Lanham Act and the FDCA - and, in particular, the question whether a Lanham Act claim can go forward if it is premised on an allegation that the defendant's labeling violates

the FDCA - can arise in district court litigation and can be decided by the regional courts of appeals. If a decision in such a case produces a conflict of authority, the Court can then consider whether its review is warranted.

To the extent that petitioners contend (Pet. 22) that their assertion of a Lanham Act claim under Section 1337 of the Tariff Act separately warrants review, that contention is misplaced. Petitioners argue (*ibid.*) that their [Section 1337](#) claim reflects a special “private right[] of action” designed to “protect domestic industry.” But petitioners misapprehend the nature of the Tariff Act provisions at issue.

Unlike a traditional private right of action (like a direct Lanham Act claim) that allows a plaintiff to sue to enforce its own rights in court, the procedure that petitioners invoked is a mechanism for seeking administrative action by the Commission. [19 U.S.C. 1337\(b\)\(1\)](#); see [*18 19 U.S.C. 1330\(d\)\(5\)](#) (investigation proceeds if “one-half of the number of commissioners voting agree that the investigation should be made”). The Commission may decline to exclude articles from the United States or to issue a cease-and-desist order, even when it has found a [Section 1337](#) violation “as a result of [its] investigation,” if the Commission concludes that the articles should not be excluded or the order should not issue in light of various public-policy considerations. [19 U.S.C. 1337\(d\)\(1\)](#); see [19 U.S.C. 1337\(e\)\(1\), \(f\)\(1\) and \(g\)\(1\)](#). And even if the Commission determines such action is warranted, the President may disapprove that determination “for policy reasons” and thus deprive the determination of any “force or effect.” [19 U.S.C. 1337\(j\)\(2\)](#).²

² Petitioners appear to dispute (Pet. 6-7) the court of appeals' holding that the Commission may decline to investigate allegations in a private complaint under [Section 1337](#) if, *inter alia*, the “complaint fails to state a cognizable claim,” Pet. App. 13; see *id.* at 11-13. But “the fact that [petitioners have] discussed this issue in the text of [their] petition for certiorari does not bring it before” this Court, because “Rule 14.1(a) requires that a subsidiary question be fairly included in the *question presented* for our review.” *Wood v. Allen*, 558 U.S. 290,304 (2010) (quoting *Izumi Seimitsu Kogyo Kabushiki Kaisha v. United States Philips Corp.*, 510 U.S. 27, 31 n.5 (1993) (per curiam)). The only question on which petitioners seek review is the logically distinct question whether a litigant asserts a cognizable Lanham Act claim under [Section 1337](#) when that claim depends on an alleged FDCA violation. Pet. i.

3. Even if review were otherwise warranted, this case would be a poor vehicle for the Court's consideration of the question presented. The court of appeals held that it had jurisdiction to hear petitioners' petition for review under [19 U.S.C. 1337\(c\)](#) and [28 U.S.C. 1295\(a\)\(6\)](#). See Pet. App. 6-10. As the dissenting judge below explained, however, the court lacked jurisdiction under [*19](#) those provisions, and it was authorized to consider only petitioners' separate petition for mandamus. See *id.* at 23-37 (Wallach, J.) (agreeing that the Commission “did not err in declining to institute an investigation,” but finding that review is limited to mandamus).

a. The Federal Circuit possesses jurisdiction to review a “final determination of the Commission under [\[Section 1337\]\(d\), \(e\), \(f\), or \(g\)](#),” using standards for judicial review set forth in the Administrative Procedure Act (APA), [5 U.S.C. 701 et seq.](#) See [19 U.S.C. 1337\(c\)](#); accord [28 U.S.C. 1295\(a\)\(6\)](#) (“final determinations of the [Commission] relating to unfair practices in import trade, made under section [1]337”). But the Tariff Act makes clear that a “final determination” under [Section 1337](#) occurs only *after* the Commission has initiated an investigation. The agency's decision not to conduct an investigation is not a reviewable “final determination.”

i. [Section 1337\(b\)](#) directs the Commission to “establish a target date for its final determination” “within 45 days after an investigation is initiated.” [19 U.S.C. 1337\(b\)\(1\)](#). That final determination is governed by [Section 1337\(c\)](#), which provides that the “Commission shall determine, with respect to each investigation conducted by it under [\[Section 1337\]](#), whether or not there is a violation of [\[Section 1337\]](#).” [19 U.S.C. 1337\(c\)](#) (emphasis added). If the Commission finds a violation after such investigation and decides to take action under [subsections \(d\)-\(g\) of Section 1337](#) - which authorize it to exclude articles from the United States, see [19 U.S.C. 1337\(d\), \(e\), and \(g\)](#), and to order a person to cease and desist violations of [Section 1337](#), see [19 U.S.C. 1337\(f\) and \(g\)](#) - the Commission must then transmit its determination to the President, who may disapprove that determination and thus strip it of any “force or effect,” [*20 19 U.S.C. 1337\(j\)\(1\)\(B\) and \(2\)](#). If the President approves the

determination or declines to disapprove it within 60 days, the Commission's determination "shall become final" "for purposes of *** [Section 1337](c)." [19 U.S.C. 1337\(j\)\(4\)](#). Under [Section 1337\(c\)](#), the Federal Circuit then has jurisdiction to review the "final determination of the Commission under [Section 1337](d), (e), (f), or (g)." [19 U.S.C. 1337\(c\)](#).

Those provisions demonstrate that the "final determination" for which the Tariff Act authorizes judicial review is the Commission's determination "after an investigation is initiated," [19 U.S.C. 1337\(b\)\(1\)](#), that the Commission must make "with respect to each investigation conducted by it," [19 U.S.C. 1337\(c\)](#). In addition, Congress has authorized review only of a "final determination of the Commission under [Section 1337](d), (e), (f), or (g)," *ibid.*, and those subsections govern the Commission's consideration of an exclusion or cease-and-desist order "during" or "as a result of an investigation." [19 U.S.C. 1337\(d\)\(1\)](#) and [\(e\)\(1\)](#); see [19 U.S.C. 1337\(f\)\(1\)](#) (action "[i]n addition to, or in lieu of," action under [Section 1337\(d\)](#) and [\(e\)](#)); [19 U.S.C. 1337\(g\)\(1\)\(B\)](#) (action after issuing "notice of investigation"). The Commission's decision not to institute an investigation thus is not a "final determination" reviewable under [Section 1337](#).

That statutory framework is consistent with the normal "presumption that agency decisions not to institute proceedings" "for investigating possible [statutory] violations" are "unreviewable" under the APA. *Heckler v. Chaney*, 470 U.S. 821, 837 (1985) (emphasis omitted). The Court in *Heckler v. Chaney* applied that principle in holding that courts could not review FDA's refusal to take enforcement actions under the FDCA. *Id.* at 828. The Tariff Act does not suggest that the Federal Circuit *21 has broader authority to review the Commission's refusal to commence an investigation here.

ii. The court of appeals largely ignored the governing statutory text. See Pet. App. 6-10; cf. *id.* at 24-31 (dissenting opinion analyzing the statutory text). The court instead deemed [Section 1337\(c\)](#)'s use of the term "final determination" to refer to a "final determination decision *on the merits* " and then concluded that the Commission's decision not to initiate an investigation in this case "is 'intrinsically a final determination, i.e., a determination *on the merits*,' " because the Commission based its decision on its view that petitioners' "complaint failed to state a cognizable claim under [Section 1]337." *Id.* at 7-8 (citation omitted). As explained above, however, the Commission declined to decide whether the challenged product label violated the Lanham Act, because resolution of that issue would have required the agency to decide an FDCA question that is reserved for FDA. In any event, whether or not the Commission's refusal to commence an investigation is properly deemed a "merits" decision, it is not the sort of "final determination" for which [Section 1337\(c\)](#) authorizes review.

b. Because the Federal Circuit lacked appellate jurisdiction, the Court could review only the court of appeals' denial of petitioners' separate petition for mandamus. See Pet. App. 11 n.3, 22. For two reasons, review of that mandamus decision would not provide the Court a suitable opportunity to resolve the question petitioners present.

First, the court of appeals stated that petitioners had "failed to explain how [they] would satisfy the traditional mandamus requirements" reflected in *Cheney v. United States District Court, supra*, see Pet. App. 11 n.3, and the court appears to have denied mandamus as *22 "moot" in light of its rejection of petitioners' contentions under normal APA review, Pet. App. 22. Cf. *id.* at 35-37 (dissenting opinion concluding that mandamus standard was not met). That limited analysis makes this case a poor vehicle to resolve the mandamus question.

Second, the mandamus standard requires that petitioners establish not only error but a "clear and indisputable" right to relief. *Cheney*, 542 U.S. at 381 (citation omitted). A determination that petitioners failed to establish a clear and indisputable right to proceed before the Commission would not definitively resolve whether the Commission correctly declined to institute an investigation based on petitioners' complaint. Perhaps for that reason, petitioners do not appear to seek this Court's review of the court of appeals' denial of their mandamus petition.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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November 2019

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TAB 4



KeyCite Yellow Flag - Negative Treatment
Distinguished by [Schwartz v. Vizio, Inc.](#), C.D.Cal., May 23, 2017

2013 WL 3654090

United States District Court, D. New Jersey.

Lynne AVRAM, on behalf of herself and
all others similarly situated, Plaintiff,

v.

SAMSUNG ELECTRONICS
AMERICA, INC., et al., Defendants.

Margaret Lark, on behalf of herself and
all others similarly situated, Plaintiff,

v.

Samsung Electronics America,
Inc., et al., Defendants.

Civ. Nos. 2:11-6973(KM), 2:12-976(KM).

July 11, 2013.

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[James J. O'Hara](#), [John Maloney](#), [Joseph Christopher Brennan](#), Graham Curtin, P.A., Morristown, NJ, for Samsung Electronics America, Inc., et al.

OPINION

[KEVIN McNULTY](#), District Judge.

*1 The Department of Energy (DOE) Energy Star program permits manufacturers of appliances, including refrigerators, to affix a label indicating that the appliance meets certain standards of energy efficiency. Such appliances, Plaintiffs allege, cost more to purchase, but supposedly save money in the long run by reducing electricity bills. Lynne Avram and Margaret Lark, putative class action plaintiffs in these consolidated actions, each bought refrigerator model RF26VAB, manufactured by Defendant Samsung Electronics

America, Inc. (“Samsung”), from Defendant Lowe's Home Centers, Inc. (“Lowe's”). At the time of purchase, the refrigerators bore the Energy Star label. Sometime thereafter, however, DOE determined that this refrigerator model did not meet the Energy Star program's requirements. Avram and Lark allege that they therefore have not received what they paid for. They assert causes of action for breach of express warranty, breach of the implied warranty of merchantability, violation of the Magnuson–Moss Warranty Act, violation of the Maryland and New Jersey consumer fraud statutes, and unjust enrichment.

Now before the court are the motions of Samsung and Lowe's to dismiss each complaint. Defendants argue that the warranty claims are preempted by the Energy Policy and Conservation Act and that the Complaints' allegations are otherwise insufficient as a matter of law.

Samsung and Lowe's motions to dismiss are granted in part and denied in part. Specifically, I will dismiss (1) Avram's claim of breach of the implied warranty of merchantability against Samsung; (2) the claims of violation of the state consumer fraud statutes; and (3) the unjust enrichment causes of action against Samsung. The rest of the claims survive.

I. BACKGROUND ¹

¹ The allegations of the Complaints have not yet been tested by any fact finder. This discussion, as it must, assumes their truth solely for the purpose of analyzing Defendant's Rule 12(b)(6) motion. See pp. 6–7, *infra*.

A. The Energy Star Program

The Energy Policy and Conservation Act of 1975 (the “ECPA”), [42 U.S.C. § 6291, et seq.](#), created an energy conservation program for major household appliances. (Avram Compl. ¶ 12 [Civ. No. 11-6973, Docket No. 1]; Lark Compl. ¶ 12 [Civ. No. 12-973, Docket No. 1]). A few years later, the National Energy Conservation Policy Act of 1978 granted the United States Department of Energy (“DOE”) the authority to establish minimum energy efficiency standards for, *inter alia*, home refrigerator-freezers. (Avram Compl. ¶ 12; Lark Compl. ¶ 12). Later, the National Appliance Energy Conservation Act of 1987 established minimum energy efficiency standards for refrigerator-freezers. (Avram Compl. ¶ 12; Lark Compl. ¶ 12).

The Energy Star program, enacted as part of the Energy Policy Act of 2005, is

a voluntary program to identify and promote energy-efficient products and buildings in order to reduce energy consumption, improve energy security, and reduce pollution through voluntary labeling of, or other forms of communication about, products and buildings that meet the highest energy conservation standards.

42 U.S.C. § 6294a. DOE and the Environmental Protection Agency (“EPA”) jointly administer the program. *Id.* In general, to earn the Energy Star label, refrigerators and freezers must be at least 20% more energy efficient than the minimum mandated by federal law. (Avram Compl. ¶ 13; Lark Compl. ¶ 13).

*2 The Energy Star logo is an important marketing tool. It conveys a message that the purchaser can maximize his or her energy savings and help to protect the environment. (Avram Compl. ¶ 14; Lark Compl. ¶ 14). In essence, the consumer pays more to purchase an Energy Star-compliant appliance, but the appliance costs less to operate. (Avram Compl. ¶ 2; Lark Compl. ¶ 2).

B. Avram's Refrigerator Purchase

Because Avram was concerned about the environment, when she shopped for a new refrigerator, she looked only at Energy Star models. (Avram Compl. ¶ 17). On June 26, 2009, Avram purchased her new refrigerator at a Lowe's retail store in Scottsdale, Arizona for \$1,213.20 plus tax. (*Id.*). That purchase price included a substantial premium based on claims that the refrigerator was energy efficient and met the qualifications of Energy Star program. (*Id.*). Avram would not have purchased the refrigerator had she known it was not Energy Star-compliant. (*Id.*).

C. Lark's Refrigerator Purchase

On November 1, 2009, Lark purchased the refrigerator at a Lowe's retail store in Maryland for about \$2,100. (Lark Compl. ¶ 17; Lark Opp. at 2). That purchase price included a substantial premium based on claims that the refrigerator

was energy efficient and met the qualifications of Energy Star program. (Lark Compl. ¶ 17).

D. DOE Finds That the Refrigerators Do Not Meet the Energy Star Program's Requirements

On February 18, 2010, DOE alerted Samsung that its testing showed that the refrigerators did not meet the Energy Star efficiency requirements. (Avram Compl. ¶ 18; Lark Compl. ¶ 18). About three weeks later, on March 8, 2010, Samsung representatives met with DOE regarding the test results. (Avram Compl. ¶ 19; Lark Compl. ¶ 19). DOE permitted Samsung to submit its own test results. (Avram Compl. ¶¶ 19–20; Lark Compl. ¶¶ 19–20) In DOE's estimation, however, Samsung's testing failed to establish that the refrigerators met Energy Star standards. (Avram Compl. ¶ 20; Lark Compl. ¶ 20). On March 16, 2010, DOE sent Samsung a letter stating that the refrigerators had failed DOE tests for the Energy Star program and that Samsung had failed to rebut that conclusion. (Avram Compl. ¶ 21; Lark Compl. ¶ 21). DOE then referred the matter to EPA for appropriate action. (Avram Compl. ¶ 21; Lark Compl. ¶ 21). EPA and Samsung eventually entered into an informal, private agreement under which Samsung agreed to stop manufacturing or selling the refrigerators. (Avram Compl. ¶ 22).

As a result, Avram and Lark did not receive the benefit of the Energy Star bargain. They paid a price premium for what purported to be an Energy Star product but did not receive the energy savings they had paid for. (Avram Compl. ¶ 23; Lark Compl. ¶ 22).

E. Avram and Lark File Class Action Complaints

On November 30, 2011, Avram filed a Complaint on behalf of herself and a class of similarly situated individuals. That Complaint alleges that Defendants' manufacture and sale of a refrigerator that falsely claimed to be Energy Star-compliant give rise to the following causes of action: breach of express warranty, breach of the implied warranty of merchantability, violations of Magnuson–Moss Warranty Act (“Magnuson–Moss”) and the New Jersey Consumer Fraud Act (“NJCFA”), and unjust enrichment.

*3 On February 17, 2012, Lark filed a nearly identical class action complaint alleging the same causes of action, with one exception. Instead of a claim under the NJCFA, Lark's complaint alleges a violation of the Maryland Consumer Protection Act (“MCPA”).

On June 20, 2012, then-Magistrate Judge Shipp granted Lark's motion to consolidate the two cases. Subject matter jurisdiction over these consolidated actions is predicated on three grounds. Over the federal law claim, the Court has federal question jurisdiction. [28 U.S.C. § 1331](#). Over the related state law claims, the Court has supplemental jurisdiction. [28 U.S.C. §§ 1337](#). Finally, because the Complaint alleges that there are over 100 class members, the aggregate amount in controversy exceeds \$5 million, and at least one class member is diverse from the defendants,² the Court has diversity jurisdiction under [28 U.S.C. § 1332\(d\)](#). Venue is proper because Samsung resides in the District of New Jersey, the Defendants do business throughout the District, and a substantial part of the events giving rise to the Plaintiffs' claims took place in New Jersey. [28 U.S.C. § 1339](#).

² Avram is a citizen of Arizona, Lark is a citizen of Maryland, Samsung is a Delaware corporation with a principal place of business in New Jersey, and Lowe's is incorporated and has its principal place of business in North Carolina.

Prior to the consolidation order and in lieu of filing an answer, Lowe's and Samsung each moved to dismiss each complaint for failure to state a claim, pursuant to [Federal Rule of Civil Procedure 12\(b\) \(6\)](#).

II. LEGAL STANDARDS AND BACKGROUND

A. Rule 12(b)(6)

[Federal Rule of Civil Procedure 12\(b\)\(6\)](#) provides for the dismissal of a complaint, in whole or in part, if it fails to state a claim upon which relief can be granted. The moving party, ordinarily the defendant, bears the burden of showing that no claim has been stated. *Hedges v. United States*, [404 F.3d 744, 750 \(3d Cir.2005\)](#). For purposes of a motion to dismiss, the well-pleaded factual allegations of the complaint must be taken as true, with all reasonable inferences drawn in plaintiff's favor. *Phillips v. County of Allegheny*, [515 F.3d 224, 231 \(3d Cir.2008\)](#) (established "reasonable inferences" principle not undermined by intervening Supreme Court case law).

In recent years, the United States Supreme Court has elaborated on the standards that a court is to apply in analyzing a [Rule 12\(b\) \(6\)](#) motion to dismiss, particularly in light of the pleading requirements of [Federal Rule of Civil Procedure 8\(a\)\(2\)](#). Although a complaint need not contain detailed factual allegations, "a plaintiff's obligation to provide

the 'grounds' of his 'entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.'" *Bell Atl. Corp. v. Twombly*, [550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 \(2007\)](#). Thus the factual allegations must be sufficient to raise a plaintiffs right to relief above a speculative level, demonstrating that it is "plausible on its face." *See id. at 570; see also Umland v. PLANCO Fin. Servs., Inc.*, [542 F.3d 59, 64 \(3d Cir.2008\)](#). A claim has "facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, [556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 \(2009\)](#) (citing *Twombly*, [550 U.S. at 556](#)). While "[t]he plausibility standard is not akin to a 'probability requirement' ... it asks for more than a sheer possibility." *Iqbal*, [556 U.S. at 678](#).

*4 The United States Court of Appeals for the Third Circuit has explicated the *Twombly/Iqbal* standard on several occasions. *See, e.g., Argueta v. U.S. Immigration & Customs Enforcement*, [643 F.3d 60, 70–73 \(3d Cir.2011\)](#); *Santiago v. Warminster Twp.*, [629 F.3d 121, 129–30 \(3d Cir.2010\)](#); *Fowler v. UPMC Shadyside*, [578 F.3d 203, 209–211 \(3d Cir.2009\)](#). The Court of Appeals recently summarized the three-step process for analyzing a [Rule 12\(b\)\(6\)](#) motion:

To determine whether a complaint meets the pleading standard, our analysis unfolds in three steps. First, we outline the elements a plaintiff must plead to a state a claim for relief. *See [Iqbal, 556 U.S.] at 675; Argueta, 643 F.3d at 73*. Next, we peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth. *See Iqbal, 556 U.S. at 679; Argueta, 643 F.3d at 73*. Finally, we look for well-pled factual allegations, assume their veracity, and then "determine whether they plausibly give rise to an entitlement to relief." *Iqbal, 556 U.S. at 679; Argueta, 643 F.3d at 73*. This last step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal, 556 U.S. at 679*.

Bistrian v. Levi, [696 F.3d 352, 365 \(3d Cir.2012\)](#).

Samsung and Lowe's assert that the state consumer protection law claims sound in fraud and therefore must be pleaded with additional particularity. *See* Section III.E, *infra*. For claims of fraud, [Federal Rule of Civil Procedure 9\(b\)](#) imposes a heightened pleading requirement, over and above that of [Rule 8\(a\)](#). Specifically, it requires that "in all averments of fraud or mistake, the circumstances constituting the fraud or mistake shall be stated with particularity." [Fed.R.Civ.P.](#)

9(b). “Malice, intent, knowledge, and other conditions of a person's mind,” however, “may be alleged generally.” *Id.* That heightened pleading standard requires the plaintiff to “state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged.” *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir.2007) (internal quotation and citation omitted).

In general, “[t]o satisfy this heightened standard, the plaintiff must plead or allege the date, time, and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.” *Id.* “Plaintiff must also allege who made the misrepresentation to whom and the general content of the misrepresentation.” *Lum v. Bank of Am.*, 361 F.3d 217, 224 (3d Cir.2004) (internal citation omitted); *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276–77 (3d Cir.2006) (“Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of fraud with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.”) (internal quotation and citation omitted)).

*5 [Plaintiffs] need not, however, plead the “date, place or time” of the fraud, so long as they use an “alternative means of injecting precision and some measure of substantiation into their allegations of fraud.” The purpose of Rule 9(b) is to provide notice of the “precise misconduct” with which defendants are charged and to prevent false or unsubstantiated charges. Courts should, however, apply the rule with some flexibility and should not require plaintiffs to plead issues that may have been concealed by the defendants.

Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir.1998) (quoting *Seville Indus. Machinery v. Southmost Machinery*, 742 F.2d 786, 791 (3d Cir.1984) and citing *Christidis v. First Pennsylvania Mortg. Trust*, 717 F.2d 96, 99 (3d Cir.1983)).

III. DISCUSSION³

³ Avram and Lark requested permission to file a surreply brief addressing new arguments and statements requiring correction that allegedly are to be found in the Defendants' reply briefs. This District's Local Rules require leave of the Court to file a surreply. See L.R. 7.1(d)(6). I find

that the Defendants' reply briefs do not raise new arguments or contain statements requiring correction. Therefore I do not authorize the filing of a surreply.

Samsung and Lowe's have filed similar motions to dismiss each count of Avram's and Lark's Complaints. I address each claim in turn, and include a choice-of-law analysis for the state law claims.

A. Preemption of Avram's and Lark's Warranty Claims

Avram and Lark assert warranty-based claims under Magnuson–Moss, as well as state-law causes of action for breach of express warranty and breach of the implied warranty of merchantability. Samsung and Lowe's argue that these claims (the “Warranty Claims”) are preempted by the ECPA, as amended by the National Appliance Energy Conservation Act (“NAECA”). Specifically, they cite 42 U.S.C. § 6297(g), which provides that any disclosure of energy use, cost, or efficiency “required to be made” pursuant to ECPA does not create an express or implied warranty. I find that the claims are not preempted because the Energy Star program is voluntary. Use of the Energy Star logo is permitted, not “required,” by the ECPA.

a. Preemption

“Federal preemption doctrine provides Congress with the power to preempt state legislation if it so intends.” *Treasurer of New Jersey v. U.S. Dep't of Treasury*, 684 F.3d 382, 406 (3d Cir.2012). Preemption comes in three varieties: “express preemption and two types of implied preemption, field preemption and conflict preemption.” *Id.* (citing *Farina v. Nokia Inc.*, 625 F.3d 97, 115 (3d Cir.2010)). Express preemption exists “when a federal enactment contains language that is explicit about its preemptive effect.” *Treasurer of New Jersey*, 684 F.3d at 406. Here, Section 6297 of NAECA contains an express preemption provision, so the issue of whether NAECA preempts the warranty claims in this case is squarely presented. *Medtronic, Inc. v. Lohr*, 518 U.S. 476, 484 (1996).

The Supreme Court has counseled courts considering a preemption issue to stick close to the text of the statute, while taking two presumptions into account.

First, the court must presume “that Congress does not cavalierly pre-empt state-law causes of action.” *Medtronic*,

518 U.S. at 485. “In all pre-emption cases, and particularly in those in which Congress has legislated ... in a field which the States have traditionally occupied’ we ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’” *Id.* at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). Conversely, the presumption against preemption may not apply where Congress’s statute applies to a field that “the States have not traditionally occupied.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347–48, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001).

*6 Second, the court must presume “that the purpose of Congress is the ultimate touchstone in every pre-emption case.” *Wyeth v. Levine*, 555 U.S. 555, 565, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009) (quoting *Medtronic*, 518 U.S. at 485). And “Congress’ intent is, of course, primarily discerned from the language of the pre-emption statute and the statutory framework surrounding it.” *Medtronic*, 518 U.S. at 485 (quotation marks and citations omitted).

Guided by these principles, I now analyze whether Avram’s and Lark’s state law warranty claims are preempted by the federal statutory regime.

i. Analysis

NAECA includes a warranty preemption provision, which states:

Any disclosure with respect to energy use, energy efficiency, or estimated annual operating cost which is required to be made under the provisions of this part shall not create an express or implied warranty under State or Federal law that such energy efficiency will be achieved or that such energy use or estimated annual operating costs will not be exceeded under conditions of actual use.

42 U.S.C. § 6297(g).

Hewing to the text of the provision, as I must, I find that Avram’s and Lark’s claims are not preempted. The Energy Star

program is voluntary; the associated disclosures of energy efficiency are not “required to be made” by statute. 42 U.S.C. § 6294a(a) (Energy Star is “a *voluntary program* to identify and promote energy-efficient products ... in order to reduce energy consumption, improve energy security, and reduce pollution through *voluntary labeling* of, or other forms of communication about, products and buildings that meet the highest energy conservation standards.”) (emphasis added). Had Congress intended to preempt warranty claims as to all such disclosures, it could simply have stated that “no disclosure *made under* the provisions of this part creates a warranty.” But it did not; it limited the preemptive effect to disclosures “*required to be made*” under the statute. I cannot assume that Congress’s insertion of the words “required to be” was accidental, or that the words themselves are superfluous and meaningless.⁴ Indeed, I can imagine a reason for it: Congress may have wished to create a safe harbor for standardized efficiency disclosures that, like automobile mileage figures, are useful for comparative purposes even if they seldom reflect what happens when the product is in use. But be that as it may, the statutory wording is clear.

⁴ Of course, if the statute contained nothing but mandatory disclosure provisions, those words could be dismissed as superfluous description. But it doesn’t; it is a mix of mandatory and non-mandatory provisions.

Samsung and Lowe’s argue that manufacturers *are* required to affix labels to their products disclosing their energy consumption, *see* 42 U.S.C. § 6296(a) (“Each manufacturer of a covered product [including refrigerators] ... shall provide a label which meets, and is displayed in accordance with, the requirements of such rule.”) (emphasis added). Of course, an appliance’s energy consumption figures will determine whether it is Energy Star-eligible. But although manufacturers are required to disclose those energy consumption figures, they are not required to participate in the Energy Star program or to affix the Energy Star logo to their products. *See* 42 U.S.C. § 6294a(a) (Energy Star is a “voluntary program” implemented through “voluntary labeling”).

*7 Plaintiffs’ claims are not based on the energy consumption disclosures, but rather on the Energy Star logo itself.⁵ This circumstance factually distinguishes other decisions that have given effect to the warranty preemption provision of Section 6297. *See Jurgensen v. Felix Storch, Inc.*, Civ. No. 12-1201, 2012 WL 2354247, at *1 (S.D.N.Y. June

14, 2012) (subsequent DOE testing determined that “Energy Guide labels to the Freezers ... ‘substantially understated their energy consumption.’”); *Gee v. Viking Range Corp.*, Civ. No. 4:07-87, 2008 WL 4416442, at *1 (N.D.Miss. Sept.24, 2008) (claims for breach of express warranty and implied warranty of merchantability based on defect in design and energy use greater than disclosed on the label). Those cases held that breach of warranty claims based on the products’ failure to live up to the manufacturers’ required disclosures of energy consumption figures were preempted by NAECA. Participation in the Energy Star Program, because it is not “required,” does not trigger the preemption provision.

5 Certain of Plaintiffs’ claims, it is true, could be read to include claims of inefficiency in operation, in addition to claims based on the inappropriateness of the Energy Star designation. I will not, however, dismiss valid claims that are arguably overbroad.

The statutory scheme is clear. A disclosure that is “required” by Congress does not create a warranty, but one (like Energy Star) that is optional may constitute an actionable warranty. A warranty claim based on such a voluntary, non-“required” disclosure is not preempted.

B. Breach of Express Warranty

I find that the Complaints sufficiently allege that the Energy Star logo constitutes an express warranty, which defendants breached. Any disclaimer in the user manual’s Limited Warranty is ineffective; at least, it cannot be presumed effective as a matter of law for purposes of a motion to dismiss.

a. Choice of Law

As to the state law claims, I must consider which state’s law applies, and I must do so separately as to each plaintiff, each defendant, and each claim. See *Gray v. Bayer Corp.*, Civ. No. 08-4716, 2011 WL 2975768, at *5 (D.N.J. July 21, 2011) (Linares, J.) (“While it might be desirable for the sake of efficiency to settle upon one state, such as New Jersey, and apply its law in lieu of the other 49 jurisdictions, due process requires individual consideration of the choice of law issues raised by each class member’s case before certification.”) (quoting *Chin v. Chrysler Corp.*, 182 F.R.D. 448, 457 (D.N.J.1998)).

“[I]n a diversity action, a district court must apply the choice of law rules of the forum state to determine what law will

govern the substantive issues of a case.” *Warriner v. Stanton*, 475 F.3d 497, 499–500 (3d Cir.2007) (citing *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941)). New Jersey uses the most significant relationship test, which consists of two prongs. *Maniscalco v. Brother Int’l Corp. (USA)*, 793 F.Supp.2d 696, 704 (D.N.J.2011) *aff’d sub nom. Maniscalco v. Brother Int’l (USA) Corp.*, 709 F.3d 202 (3d Cir.2013). First, the court must determine whether a conflict actually exists between the potentially applicable laws. *P.V. v. Camp Jaycee*, 197 N.J. 132, 144, 962 A.2d 453, 460 (2008) (“Procedurally, the first step is to determine whether an actual conflict exists. That is done by examining the substance of the potentially applicable laws to determine whether there is a distinction between them.”) (internal quotations omitted). “[I]f no conflict exists, the law of the forum state applies.” *Snyder v. Farnam Companies, Inc.*, 792 F.Supp.2d 712, 717 (D.N.J.2011) (quoting *P.V.*, 197 N.J. at 143, 962 A.2d at 453).

*8 If a conflict exists, the court then moves to the second prong: it must determine “which state has the ‘most significant relationship’ to the claim at issue by weighing the factors” in the applicable section of the Restatement (Second) of Conflict of Laws. For contract actions, the applicable section is Restatement § 188. *Gilbert Spruance Co. v. Pennsylvania Mfrs. Ass’n Ins. Co.*, 134 N.J. 96, 102, 629 A.2d 885, 888 (1993).

Under New Jersey law, to state a claim for breach of express warranty, “Plaintiffs must properly allege: (1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description.” *Snyder*, 792 F.Supp.2d at 721 (citing N.J. Stat. Ann. § 12A:2-313) (other internal citation omitted). Arizona and North Carolina law are substantially similar. See *Ariz.Rev.Stat. Ann. § 47-2313* (defining an express warranty as “[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain” or “[a]ny description of the goods which is made part of the basis of the bargain.”); *N.C. Gen.Stat. Ann. § 25-2-313* (same).

The parties do not identify any significant distinction among these states’ laws with respect to this issue. For the purposes of the pending motions,⁶ with respect to a claim of breach of express warranty, no significant conflict exists between the laws of Arizona, North Carolina and New Jersey.

Accordingly, I will apply the law of the forum state, New Jersey. *See, e.g., Snyder, 792 F.Supp.2d at 717.*

6 “Applying the factors necessary to determine choice of law for a contract or quasi-contract claim” may be “a very fact-intensive inquiry,” such that the analysis sometimes is more appropriate at the class certification stage. *Snyder v. Farnam Companies, Inc., 792 F.Supp.2d 712, 721 (D.N.J.2011).* Nevertheless, “[s]ome choice of law issues may not require a full factual record and may be amenable to resolution on a motion to dismiss.” *Harper v. LG Electronics USA, Inc., 595 F.Supp.2d 486, 491 (D.N.J.2009).* This is determined issue-by-issue. *Arlandson v. Hartz Mountain Corp., 792 F.Supp.2d 691, 700 (D.N.J.2011).* These Complaints, I find, contain allegations sufficient to permit a choice-of-law determination.

b. Analysis

Avram's and Lark's allegations are straightforward: The Energy Star logo was an affirmation that the product was Energy Star compliant; they purchased the refrigerators because of the logo; and the refrigerators did not, in fact, meet the Energy Star requirements. The parties dispute, however, whether the allegations establish the first two elements of a breach of express warranty: that the seller made an affirmation or promise about the product, and that it became the basis of the bargain.

i. Energy Star Logo as an Affirmation or Promise

“A statement can amount to a warranty, even if unintended to be such by the seller, ‘if it could fairly be understood ... to constitute an affirmation or representation that the [product] possesse[s] a certain quality or capacity relating to future performance.’ ” *L.S. Heath & Son, Inc. v. AT & T Info. Sys., Inc., 9 F.3d 561, 570 (7th Cir.1993)* (applying New Jersey law and quoting *Gladden v. Cadillac Motor Car Div., General Motors Corp., 416 A.2d 394, 396, 83 N.J. 320 (1980)*). “[W]hether a given statement constitutes an express warranty is normally a question of fact for the jury.” *Snyder v. Farnam Companies, Inc., 792 F.Supp.2d 712, 721–22 (D.N.J.2011); see also Union Ink Co., Inc. v. AT & T Corp., 352 N.J.Super. 617, 645, 801 A.2d 361 (App.Div.2002)* (“Whether the advertisements contained material misstatements of fact, or were merely puffing, as alleged by defendants, presents a question to be determined by the trier of fact.”).

*9 Avram's and Lark's Complaints allege that refrigerators that carry the Energy Star logo meet the program's requirements of using 20% less energy than the minimum federal standard. (Avram Compl. ¶ 2; Lark Compl. ¶ 2). The refrigerators were sold with the logo, but subsequent DOE testing revealed that they did not meet Energy Star efficiency requirements. (Avram Compl. ¶ 1; Lark Compl. ¶ 1). The Complaints sufficiently allege that, by attaching the Energy Star label to the refrigerators, Samsung and Lowe's affirmed that the refrigerators qualified for the program. *See Taylor v. JVC Americas Corp., Civ. No. 07–4059, 2008 WL 2242451, at *5 (D.N.J. May 30, 2008)* (warranty claim sufficiently pled by allegations that packaging said the product was a “1080p” television, but television did not accept a 1080p signal).

Defendants cite two cases in which courts held that the Energy Star logo did not support a claim of breach of express warranty. I find them distinguishable.

In *Savett v. Whirlpool Corp., Civ. No. 12–310, 2012 WL 3780451 (N.D.Oh. Aug. 31, 2012)*, the court simply found that the complaint simply failed to allege any particular statement or promise that the logo conveyed. *Id. at *9.* Here, by contrast, the Complaints allege that the Energy Star logo conveys that the refrigerator is at least 20% more energy efficient than the minimum federal standard.⁷ *Rossi v. Whirlpool Corp., Civ. No. 12–125, 2013 WL 1312105 (E.D.Cal. Mar. 28, 2013)* applies California law in a manner that does not square with cases from this District that apply New Jersey law. *See Hemy v. Perdue Farms, Inc., Civ. No. 11–888, 2013 WL 1338199, at *7, *10 (D.N.J. Mar. 31, 2013)* (complaint sufficiently alleges that a “humanely raised” label would be understood by consumers to encompass the slaughtering process); *Taylor, supra, 2008 WL 2242451 at *5.*

7 Avram's and Lark have, in addition, asked the court to take judicial notice of DOE survey results that show that the majority of households understand and rely on Energy Star labels when making purchasing decisions. (*See National Awareness of Energy Star for 2011: Analysis of CEE Household Survey, Ex. C to Request for Judicial Notice at ES–1 to ES–1 [Docket No. 37–4]*). Such information might provide further support of Plaintiffs' position, but is not necessary for purposes of this motion.

Applying New Jersey law, I find that the Complaints adequately allege that the Energy Star logo would be

understood by consumers as an affirmation of fact or a promise regarding the energy efficiency of the refrigerators.

ii. *Basis of the Bargain*

“Under New Jersey law, a representation is presumed to be part of the basis of the bargain ‘once the buyer has become aware of the affirmation of fact or promise’ and can be rebutted by ‘clear affirmative proof that the buyer knew that the affirmation of fact or promise was untrue.’ ” *Viking Yacht Co. v. Composites One LLC*, 496 F.Supp.2d 462, 469 (D.N.J.2007) (quoting *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 171 F.3d 818, 825 (3d Cir.1999) (other internal quotation omitted)).

Samsung and Lowe's contend that the Complaints fail to allege that the Energy Star logo was part of the basis of the bargain. Avram, however, alleges that she had decided to purchase only a refrigerator that sported the Energy Star label. (Avram Compl. ¶ 17). While Lark did not limit her search in the same way, one can reasonably infer from her complaint that she knew the Energy Star label was on the refrigerator, understood its meaning, and paid a higher price based on it. (See, e.g., Lark Compl. ¶ 17 (Lark's purchase of the refrigerator “included a substantial price premium due to its supposed energy efficiency and ENERGY STAR® qualification.”)). Defendants did not—indeed, at this procedural stage, probably could not—rebut the allegations by proving that Avram and Lark were not in fact misled. That is not to say that such a rebuttal could not eventually be made, but, at this stage, I find that Avram and Lark have stated a claim for breach of express warranty.

iii. *Disclaimer via Samsung's Limited Warranty*

*10 Only one point remains: whether Samsung successfully disclaimed the warranty. Samsung and Lowe's argue that, by offering a Limited Warranty that expressly disclaims all others, Samsung effectively negated any warranty based on the Energy Star logo.

Both the UCC and New Jersey law allow manufacturers to limit their liability (other than for personal injury) through disclaimers. *Alloway v. Gen. Marine Indus., L.P.*, 149 N.J. 620, 630, 695 A.2d 264, 269 (1997); see N.J. Stat. Ann. § 12A:2–316. Such a disclaimer must be so clear and conspicuous that a reasonable purchaser would notice it. *Gladden v. Cadillac Motor Car Div.*, 83 N.J. 320, 331, 416 A.2d 394, 400 (1980).

The refrigerator's manual states that “Energy star labeled this product could save your energy costs.” [sic] (User Manual at 2, Ex. A to O'Hara Dec. [Docket No. 6-2]).⁸ The Limited Warranty in the manual “covers manufacturing defects in materials and workmanship encountered in normal, noncommercial use of the product.” (*Id.* at 42). The Limited Warranty contains an express disclaimer: “THERE ARE NO EXPRESS WARRANTIES OTHER THAN THOSE LISTED AND DESCRIBED ABOVE.... SAMSUNG SHALL NOT BE LIABLE FOR ... FAILURE TO REALIZE SAVINGS OR OTHER BENEFITS....” (*Id.* at 43).

⁸ The Limited Warranty is not referred to in either complaint and therefore would not ordinarily be considered as part of a motion to dismiss. I nevertheless consider it, but find it ineffective as a disclaimer.

“[U]nder U.C.C. § 2–316, a warranty disclaimer inconsistent with an express warranty is inoperative.” *L.S. Heath & Son, Inc. v. AT & T Info. Sys., Inc.*, 9 F.3d 561, 570 (7th Cir.1993) (citing N.J. Stat. Ann. § 12A:2–316); *Gladden*, 83 N.J. at 330, 416 A.2d at 399. Because I have found that the Energy Star logo constitutes an express warranty, this attempt to disclaim it would be ineffective.⁹ I note, too, the potential for unfairness if an express warranty is displayed to the purchaser when he parts with his money at the store, but the disclaimer appears at page 42 of a manual sealed inside the product's packaging. At best, such an alleged disclaimer would present an issue of fact. Either way, the motion to dismiss must be denied.

⁹ The Limited Warranty covers parts and labor on the refrigerator generally for one year, and on the sealed refrigeration system for five years. (*Id.* at 42). I do not reach the issue of whether these claims, if brought under the Limited Warranty, would be untimely.

C. Breach of the Implied Warranty of Merchantability

Samsung and Lowe's argue that the implied warranty of merchantability claims should be dismissed because neither complaint adequately alleges that the refrigerators failed in their “ordinary purpose,” which is to keep food cold. Avram and Lark respond that this appliance was sold as a high-efficiency refrigerator with a more particular ordinary purpose: to keep food cold *in compliance with Energy Star efficiency standards*. As to each plaintiffs claim against each

defendant, I must determine I must first determine which state's law applies. I conclude that New Jersey law governs both plaintiffs' implied warranty claims against Lowe's, as well as Lark's claim against Samsung. Avram's claim against Samsung, however, is governed by Arizona law.

1. Avram's implied warranty claim against Samsung

Avram, a citizen of Arizona, asserts a state law implied warranty of merchantability claim against Samsung, a citizen of New Jersey, in a New Jersey federal court.

*11 I must first determine which law applies—New Jersey's or Arizona's. The first step is to see whether these two states' laws conflict. *P.V. v. Camp Jaycee*, 197 N.J. 132, 144, 962 A.2d 453, 460 (2008). They do. For an implied warranty of merchantability claim, Arizona requires contractual privity, but New Jersey does not. *Compare Flory v. Silvercrest Indus.*, 129 Ariz. 574, 579, 633 P.2d 383, 388 (1981) (“economic losses are not recoverable for breach of implied warranty in the absence of privity of contract”) with *Spring Motors Distributors, Inc. v. Ford Motor Co.*, 98 N.J. 555, 582, 489 A.2d 660, 674 (1985) (“We conclude that the absence of privity between a remote supplier and an ultimate purchaser should not preclude the extension to the purchaser of the supplier's warranties made to the manufacturer.”) The conflict matters because Avram (who purchased the refrigerator from Lowe's) is not in privity with Samsung (the remote manufacturer of the refrigerator).

Having established that a conflict exists, the Court must determine “which state has the ‘most significant relationship’ to the claim at issue by weighing the factors” in Section 188 of the Restatement (Second) of Conflict of Laws. *Gilbert Spruance Co. v. Pennsylvania Mfrs. Ass'n Ins. Co.*, 134 N.J. 96, 102, 629 A.2d 885, 888 (1993). Those factors are: “(1) the place of contracting, (2) the place of negotiation of the contract, (3) the place of performance, (4) the location of the subject matter of the contract, and (5) the domicile, residence, nationality, place of incorporation and place of business of the parties.” *Spence-Parker v. Delaware River & Bay Auth.*, 656 F.Supp.2d 488, 498–99 (D.N.J.2009) (citing Restatement (Second) of Conflicts § 188(2)).

Those factors point to the conclusion that Arizona law applies to Avram's claim against Samsung. Avram shopped for, purchased, installed and used the refrigerator in Arizona, where she lives. Those facts imply that the first four factors favor Arizona. The last factor—the residence and place of incorporation of the parties—is more or less neutral, in that

one party is a citizen of Arizona, and the other of New Jersey (the co-plaintiff and co-defendant are located elsewhere). Accordingly, Arizona law will apply to Avram's claim of breach of the implied warranty of merchantability as against Samsung.

Avram's implied warranty claim against Samsung falls afoul of Arizona's requirement of privity of contract. *See Flory, supra*. Privity does not exist because Avram purchased her refrigerator from Lowe's, not Samsung. (Avram Compl. ¶ 17). Accordingly, her breach of warranty claim against Samsung, the remote manufacturer, must be dismissed. *See Haugland v. Winnebago Indus.*, 327 F.Supp.2d 1092, 1097 (D.Ariz.2004) (because “privity is absent in this case, Plaintiffs implied warranty of merchantability claims ... will be dismissed.”); *Yee v. Nat'l Gypsum Co.*, Civ. No. 09–8189, 2010 WL 2572976, at *2 (D.Ariz. June 22, 2010) (dismissing implied warranty claim against manufacturer because plaintiff “cannot [establish privity] because he bought the drywall not from [the manufacturer], but from Lowe's.”).

2. Lark's implied warranty claim against Samsung and both Plaintiffs' implied warranty claims against Lowe's

*12 The remaining implied warranty of merchantability claims—Lark's claim against Samsung and both plaintiffs' claims against Lowe's—present “false conflicts.” They are therefore governed by the law of the forum state, New Jersey.

Lark, a citizen of Maryland, sues Samsung, a citizen of New Jersey, for breach of the implied warranty of merchantability. For purposes of this claim, there is no significant difference between Maryland and New Jersey law. *Compare Pulte Home Corp. v. Parex, Inc.*, 174 Md.App. 681, 755, 923 A.2d 971, 1013 (2007) (“In an action based on breach of warranty it is necessary for the plaintiff to show the existence of the warranty, the fact that the warranty was broken and that the breach of warranty was the proximate cause of the loss sustained.”), with *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 601 n. 8 (3d Cir.2012) (“To state a claim for breach of the implied warranty of merchantability, a plaintiff must allege (1) that a merchant sold goods, (2) which were not ‘merchantable’ at the time of sale, (3) injury and damages to the plaintiff or its property, (4) which were caused proximately and in fact by the defective nature of the goods, and (5) notice to the seller of injury.” (internal citation and quotation omitted)). Accordingly, New Jersey law will govern Lark's claim against Samsung for breach of the

implied warranty of merchantability. *See Snyder v. Farnam Companies, Inc.*, 792 F.Supp.2d 712, 717 (D.N.J.2011).

As to Avram's and Lark's implied warranty claims against Lowe's, North Carolina law is added to the mix; Lowe's is incorporated and has its principal place of business in North Carolina. Unlike New Jersey, but like Arizona, North Carolina requires privity. *Compare Spring Motors Distributors, Inc. v. Ford Motor Co.*, 98 N.J. 555, 582, 489 A.2d 660, 674 (1985) ("We conclude that the absence of privity between a remote supplier and an ultimate purchaser should not preclude the extension to the purchaser of the supplier's warranties made to the manufacturer."), and *Ace Am. Ins. Co. v. Grand Banks Yachts, Ltd.*, 587 F.Supp.2d 697, 705 (D.Md.2008) ("Maryland has expressly abolished the requirement for contractual privity to sue for breach of the implied warranty of merchantability" (citing *Md.Code Ann., Com. Law § 2-314(1)(b)* ("Any previous requirement of privity is abolished as between the buyer and the seller in any action brought by the buyer."))), with *Kelly v. Georgia-Pac. LLC*, 671 F.Supp.2d 785, 796 (E.D.N.C.2009) ("Under North Carolina common law, privity of contract is generally required to assert an implied warranty claim.").

With respect to claims against Lowe's, however, this is a "false conflict," wherein "the laws of the two jurisdictions would produce the same result on the particular issue presented." *Williams v. Stone*, 109 F.3d 890, 893 (3d Cir.1997). Avram and Lark bought their refrigerators from Lowe's and are in privity with Lowe's; lack of privity is therefore a non-issue. Accordingly, I will disregard the nominal conflict with North Carolina law; New Jersey law will govern Avram's and Lark's claims against Lowe's for breach of the implied warranty of merchantability.

*13 "[T]he UCC, as adopted by New Jersey, specifically states that an implied warranty of merchantability ensures that goods sold are 'fit for the ordinary purposes for which such goods are used.' " *Arlandson v. Hartz Mountain Corp.*, 792 F.Supp.2d 691, 706 (D.N.J.2011) (quoting *N.J. Stat. Ann. § 12A:2-314(f)*). It "does not impose a general requirement that goods precisely fulfill the expectation of the buyer. Instead, it provides for a minimum level of quality." *Lieberson v. Johnson & Johnson Consumer Companies, Inc.*, 865 F.Supp.2d 529, 542 (D.N.J.2011) (internal quotations and citations omitted). Put a different way, "merchantability is defined as the product sold 'should be of the general kind described and reasonably fit for the general purpose for which it should have been sold.' " *Id.* (quoting *Adams v. Peter*

Tramontin Motor Sales, Inc., 42 N.J.Super. 313, 321, 126 A.2d 358 (App.Div.1956) (emphasis added) (other internal quotation and citation omitted). Generally, a court will find a good to be unfit for its ordinary purpose "when [it] can identify one of three general types of defects: manufacturing defects, design defects, and failure to give the buyer proper instructions with respect to the goods." *Lieberson*, 865 F.Supp.2d at 542.

But what is the general, "ordinary purpose" of these refrigerators? Self-evidently, they are designed to keep perishables cold, and no one contends that they failed to do that. Avram and Lark, however, stress that these refrigerators were sold as high-efficiency appliances that would keep food cold in accordance with Energy Star efficiency standards. And they did allegedly fail to do that.

An impairment of the "ordinary purpose" of a product is one that is central to the product's value or function. *Compare Zabriskie Chevrolet, Inc. v. Smith*, 99 N.J.Super. 441, 450, 240 A.2d 195, 200 (Law Div.1968) (where the car the plaintiff purchased broke down less than a mile from the dealership, the car was "substantially defective" and in breach of the implied warranty of merchantability), with *Green v. Green Mountain Coffee Roasters, Inc.*, 279 F.R.D. 275, 283 (D.N.J.2011) (rejecting implied warranty of merchantability claim that a single-cup brewing system, although it brewed beverages, failed to brew precisely one cup), and *Lieberson*, 865 F.Supp.2d at 543 (finding no breach of the implied warranty of merchantability where soap and lotion did not help babies sleep, as advertised, because the soap was "clearly manufactured for the purpose of washing and moisturizing babies' skin" and it did do that).

Based on the allegations in the Complaints, I find that the Energy Star label puts the refrigerators closer to the car in *Zabriskie* than to the coffeemaker in *Green* or the soap in *Lieberson*. Soporific qualities and precise portion control do not, so far as I am aware, embody any settled consumer expectation as to baby soap or coffee makers. (Avram Compl. ¶ 1; Lark Compl. ¶ 1). An Energy Star sticker, by contrast, stands for a level of efficiency, defined in relation to statutory standards, for which consumers allegedly are willing to pay a premium. (Avram Compl. ¶ 2; Lark Compl. ¶ 2). The eventual presentation of evidence might or might not establish Plaintiffs' claim; I cannot say, however, that they have failed to state one.

*14 Accordingly, I dismiss Avram's claim of breach of the implied warranty of merchantability as against Samsung under Arizona law. The remaining implied warranty claims, analyzed under New Jersey law, meet federal pleading requirements and will not be dismissed.

D. Magnuson–Moss Warranty Act Claims

Magnuson–Moss is “a remedial statute designed to protect the purchasers of consumer goods from deceptive warranty practices.” *Miller v. Willow Creek Homes, Inc.*, 249 F.3d 629, 630 (7th Cir.2001) (citation omitted). It provides for a private right of action whenever when a purchaser is “damaged by the failure of a ... warrantor ... to comply with any obligation under [Magnuson–Moss], or under a written warranty” 15 U.S.C. § 2310(d)(1). Logically, “Magnuson–Moss claims based on breaches of express and implied warranties under state law depend upon those state law claims.” *Cooper v. Samsung Elec. Am., Inc.*, Civ. No. 07–3853, 2008 WL 4513924, at *6 (D.N.J. Sept. 30, 2008) (citing *In re Ford Motor Co. Ignition Switch Prods. Liability Litig.*, 19 F.Supp.2d 263, 267 (D.N.J.1998)).

Samsung and Lowe's argue that Plaintiffs' Magnuson–Moss claims are based on invalid state-law warranty claims, and therefore should be dismissed. As discussed in Sections III.B and C, above, however, all but one of the state-law causes of action for breach of express and implied warranties are legally sufficient and they will not be dismissed. Consequently, the Magnuson–Moss claim survives as well.

In addition, the Magnuson–Moss claims meet federal pleading standards. A “written warranty” is:

(A) any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time ...

which ... becomes part of the basis of the bargain between a supplier and a buyer for purposes other than resale of such product.

15 U.S.C. § 2301(6).

The allegations of the Complaint easily would support an inference that the refrigerators are consumer products

and the Defendants are suppliers within the meaning of the statute.¹⁰ As discussed in Section III.B, above, the Complaints adequately allege that the Energy Star logo constitutes a written affirmation of fact relating to the refrigerators' performance that became part of the basis of the bargain.

¹⁰ “Consumer product” is defined as any tangible personal property which is distributed in commerce and which is normally used for personal, family, or household purposes (including any such property intended to be attached to or installed in any real property without regard to whether it is so attached or installed). 15 U.S.C. § 2301(1). A “supplier” is any person engaged in the business of making a consumer product directly or indirectly available to consumers. 15 U.S.C. § 2301(4).

The Complaints state claims under Magnuson–Moss. Samsung and Lowe's motions to dismiss the Magnuson–Moss claims are denied.

E. State Consumer Protection Statute Claims

a. Avram's New Jersey Consumer Fraud Act Claim

Avram brings a claim under the New Jersey Consumer Fraud Act against Samsung only. I find that the law of Arizona applies, and that the NJCFA claim must therefore be dismissed as a matter of law.¹¹

¹¹ Should New Jersey law apply, Samsung argues, the NJCFA claim should be dismissed because it does not state an ascertainable loss nor are its allegations pleaded with particularity. Because I find that Arizona law applies, I do not reach those issues.

*15 Step one of the choice-of-law analysis requires the Court to determine if an actual conflict exists between New Jersey and Arizona law. As both parties acknowledge, there is a conflict. The Arizona Consumer Fraud Act (the “ACFA”) (1) requires reliance, *Kuehn v. Stanley*, 208 Ariz. 124, 129, 91 P.3d 346, 351 (Ct.App.2004) (“An injury occurs when a consumer relies, even unreasonably, on false or misrepresented information.”); (2) has a one-year statute of limitations, *Cervantes v. Countrywide Home Loans, Inc.*, 656 F.3d 1034, 1045 (9th Cir.2011); (3) does not permit treble damages and (4) allows only the attorney general to collect attorneys' fees. Ariz.Rev.Stat. Ann. § 44–1534.

New Jersey, by contrast, (1) does not require reliance, *Lieberson v. Johnson & Johnson Consumer Companies, Inc.*, 865 F.Supp.2d 529, 538 (D.N.J.2011) (stating elements of NJCFA claim, which do not include reliance); (2) has a six-year statute of limitations, *Dilorio v. Structural Stone & Brick Co., Inc.*, 368 N.J.Super. 134, 142, 845 A.2d 658, 663 (App.Div.2004); (3) imposes treble damages and (4) provides for an award of attorneys' fees. *N.J. Stat. Ann. § 56:8-19*.

In short, the ACFA and the NJCFA conflict. Accordingly, I move to step two to see which state has the most significant relationship to the claim, using the factors outlined in the applicable subsection of Section 148 of the Restatement (Second) of Conflict of Laws. *Maniscalco v. Brother Int'l Corp. (USA)*, 793 F.Supp.2d 696, 704 (D.N.J.2011) (citing *P.V. v. Camp Jaycee*, 197 N.J. 132, 143–44, 962 A.2d 453, 460 (2008)).

The subsection of the Restatement that applies to this case is Section 148(2),¹² which states:

¹² Restatement Section 148(1) states:

(1) When the plaintiff has suffered pecuniary harm on account of his reliance on the defendant's false representations and when the plaintiff's action in reliance took place in the state where the false representations were made and received, the local law of this state determines the rights and liabilities of the parties unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in § 6 to the occurrence and the parties, in which event the local law of the other state will be applied.

I find that Section 148(1) does not apply, because the representations and the reliance did not both occur in any single state. Any representations were made in New Jersey, but received in Arizona, where Avram allegedly relied upon them. To the extent that that the applicability of Section 148(1) is suggested by *Agostino v. Quest Diagnostics, Inc.*, 256 F.R.D. 437 (D.N.J.2009), I find the case distinguishable. See *Maniscalco*, 793 F.Supp.2d 696, 707 (distinguishing *Agostino* because the *Agostino* defendant "intended the fraudulent bills be read by each plaintiff in his or her home state," while the facts in *Maniscalco* did "not concern the direct targeting of plaintiffs whose identities and

addresses [were] known."). There is no evidence that Samsung or Lowe's directly and knowingly targeted Avram or anyone else.

(2) When the plaintiff's action in reliance took place in whole or in part in a state other than that where the false representations were made, the forum will consider such of the following contacts, among others, as may be present in the particular case in determining the state which, with respect to the particular issue, has the most significant relationship to the occurrence and the parties:

- (a) the place, or places, where the plaintiff acted in reliance upon the defendant's representations,
- (b) the place where the plaintiff received the representations,
- (c) the place where the defendant made the representations,
- (d) the domicile, residence, nationality, place of incorporation and place of business of the parties,
- (e) the place where a tangible thing which is the subject of the transaction between the parties was situated at the time, and
- (f) the place where the plaintiff is to render performance under a contract which he has been induced to enter by the false representations of the defendant.

Restatement (Second) of Conflict of Laws § 148(2) (1971). Simple factor-counting is not the whole of the analysis, but it is a starting point. Four of the *Section 148(2)* factors favor the application of Arizona law, one favors New Jersey, and one is neutral. Specifically, the first two and last two favor Arizona law: in Arizona, Avram received the representations and acted in reliance on them in purchasing and using the refrigerator. The third factor—that Samsung made the representations in New Jersey—favors New Jersey law. The remaining factor—the residence, place of incorporation, and place of business of the parties—is evenly balanced. In sum, the 148(2) factors point to Arizona law.

*¹⁶ Courts are also admonished, however, not merely to count the 148(2) factors, but to weigh them in light of the principles stated in Section 6 of the Restatement. *Camp Jaycee*, 197 N.J. at 147, 962 A.2d at 463; see also Restatement § 148 cmt. B. Those policies are:

- (a) the needs of the interstate and international systems,
- (b) the relevant policies of the forum,
- (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
- (d) the protection of justified expectations,
- (e) the basic policies underlying the particular field of law,
- (f) certainty, predictability and uniformity of result, and
- (g) ease in the determination and application of the law to be applied.

Restatement (Second) of Conflict of Laws § 6. “Reduced to their essence, the § 6 principles are: (1) the interests of interstate comity; (2) the interests of the parties; (3) the interests underlying the field of tort law; (4) the interests of judicial administration; and (5) the competing interests of the states.” *Camp Jaycee*, 197 N.J. at 147, 962 A.2d at 463.

Avram's Arizona residence weighs heavily in favor of that state's law. “The interests of interstate comity favor applying the law of a state where the injured party resides.” *Montich v. Miele USA, Inc.*, 849 F.Supp.2d 439, 450 (D.N.J.2012) (citing *Fink v. Ricoh Corp.*, 365 N.J.Super. 520, 585, 839 A.2d 942 (Law Div.2003) (stating this factor “clearly require[s] application of the law of any potential claimant's state of residence because application of any other state's law would frustrate the domiciliary state's legislative policies....”)).

The second factor, the interests of the parties, looks to the law the parties reasonably expected would apply. *See Fu v. Fu*, 160 N.J. 108, 123, 733 A.2d 1133 (1999); *see also* Restatement § 6, comment g (“Generally speaking, it would be unfair and improper to hold a person liable under the local law of one state when he had justifiably molded his conduct to conform to the requirements of another state.”). It is given more weight in the context of a voluntary commercial transaction, like this one, in which the parties can be said to have “molded” their conduct, as opposed to, say, a personal-injury tort case. *See Agostino*, 256 F.R.D. at 463 (“the interests of the parties ‘is of extreme importance in the field of contracts,’ but it ‘plays little or no part in a choice-of-law question in the field of torts.’ ” (quoting *Fu v. Fu*, 160 N.J. 108, 123, 733 A.2d 1133, 1141 (2009) (internal quotation omitted)). Avram purchased, took delivery of, and

used the refrigerator in Arizona, and Samsung surely knew its products would be sold there; the application of Arizona law defeats no legitimate expectation of either party. Conversely, I see no indication that Avram knew where Samsung was headquartered, or that she ever dreamed that her refrigerator purchase bore any relation to New Jersey or its laws.

*17 The third factor focuses on which law would further the “fundamental goals of tort law,” which are deterrence and compensation. *Id.* Taken literally, this factor might imply that the more plaintiff-favorable law always wins. But the determination is more systematic and respectful of state policy judgments. True, NJCFA is probably more generous to plaintiffs and stern with manufacturers than is the ACFA. But “[s]imply because New Jersey has struck a particular balance between consumer protection and the promotion of business within its borders does not suggest that its interest in deterrence should displace the policy goals of its fellow states. Those states have instead struck their own legislative balances, awarding compensation based on differing standards of, *inter alia*, intent, causation, reliance, and damages.” *Gray v. Bayer Corp.*, Civ. No. 08-4716, 2011 WL 2975768, at *5 (D.N.J. July 21, 2011). Avram had no contacts with New Jersey, but substantial ones with Arizona. She directly purchased the refrigerator from a third party with no ties to New Jersey. Application of ACFA would further Arizona's interest in compensating purchasers for harms they may have suffered. New Jersey's interest, however, in compensating out-of-state consumers is minimal, and the state's contacts with this litigation have come only because Samsung's headquarters happen to be located there. I thus see “little reason to conclude that New Jersey's deterrent interest with respect to one party should be elevated above” Arizona's. *See id.* In other words, this factor is at best neutral, but tends to lean in favor of Arizona.

The fourth factor is neutral. There is no indication that the interests of judicial administration favor either state.

Fifth, the states' competing interests also tilt to Arizona. “[E]very state has an interest in having its law applied to its resident claimants.” *Montich v. Miele USA, Inc.*, 849 F.Supp.2d 439, 450 (internal quotation and citation omitted). Arizona, the state where the plaintiff “claimant” resides, and where the bulk of the contacts occurred, has the stronger interest in protecting its consumers from harm, regulating incursions by foreign corporations, and determining the scope of recovery for its citizens. *See id.* (citing *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422, 123 S.Ct.

1513, 155 L.Ed.2d 585 (2003) (“[E]ach State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders.”)).

In short, I apply New Jersey conflicts law and find that the Restatement § 148(2) factors, interpreted in light of the policies stated in § 6, strongly point to the application of Arizona law. Other judges in this District, analyzing analogous cases, have come to a similar conclusion. *See, e.g.*, *Agostino*, 256 F.R.D. at 463 (Chesler, J.); *Gray v. Bayer Corp.*, Civ. No. 08-4716, 2011 WL 2975768, at *5 (D.N.J. July 21, 2011) (Linares, J.).

Avram, however, cites *In re Mercedes-Benz Tele Aid Contract Litigation*, 257 F.R.D. 46 (D.N.J.2009) (Debevoise, J.), which applied the NJCFA to a claim that a New Jersey corporation had made in-state misrepresentations affecting an out-of-state plaintiff. There, Judge Debevoise found that, under the circumstances, the actions emanating from New Jersey and this State's strong interest in regulating its corporations outweighed other, contrary factors. *See id.* at 64-70. The facts of *Mercedes-Benz* are distinguishable in my view. There, the defendant's extensive, possibly nefarious steps in New Jersey might have lent greater weight to this State's interest in regulating domestic corporations. *Id.* at 51-54, 66. More to the point, no subsequent case has followed *Mercedes-Benz*, and many have found that its reasoning went too far. *See, e.g.*, *Montich v. Miele USA, Inc.*, 849 F.Supp.2d 439, 449-50 (D.N.J.2012) (collecting criticism of, and distinguishing, *Mercedes-Benz*, and finding, “[b]ased on these facts and the weight of the precedent in this Circuit,” that California law applied where “Plaintiff purchased the washing machine from a store in California, took delivery of the machine in California, used the machine at her home in California, and allegedly suffered injury in California.”); *In re Vioxx Products Liab. Litig.*, 861 F.Supp.2d 756, 765 (E.D.La.2012) (declining to apply the NJCFA and stating “only one factor seems to weigh in favor of the application of New Jersey law. This was enough for the *Mercedes-Benz* court to apply New Jersey law to out-of-state litigants, but as noted above that opinion is an outlier. Under similar facts, many more cases have applied the consumer fraud law of plaintiffs home state.”); *Gray v. Bayer Corp.*, 2011 WL at *6 (“While this Court agrees with the court in *Mercedes-Benz* that due consideration must be given to New Jersey's deterrent interest in enforcing the NJCFA, the Court concludes that, given the substantial contacts between Plaintiff's claims and the states where One-A-Day WeightSmart was purchased, to disregard the individual laws of those states in favor of a blanket application of New

Jersey law would ignore their strong compensatory interest in this matter and would threaten to upset the balance of our federal system. The Court thus follows the weight of authority counseling against the application of the NJCFA to out-of-state consumers.”); *Moloney v. Microsoft Corp.*, No. 09-2047, 2011 WL 5864064, at *9, 2011 U.S. Dist. LEXIS 134841, at *28 (D.N.J. Nov. 21, 2011) (“This Court is similarly unsatisfied with the justifications provided in the *Mercedes-Benz* decision.”); *Agostino v. Quest Diagnostics Inc.*, No. 04-4362, 2010 WL 5392688, *9, 2010 U.S. Dist. LEXIS 135310, *28 (D.N.J. Dec. 22, 2010) (“Parting ways, however, with Judge Debevoise's assessment in *Mercedes*, this Court does not consider that New Jersey's interest in deterring fraudulent conduct perpetrated by domestic companies necessarily trumps the interest of the victim's home state.”).

*18 Like the judges in the cases cited above, I find that New Jersey has the less significant relationship with Avram's consumer fraud claim. “[A]ccepting all of the facts as pleaded by Plaintiffs as true, the factors weigh in favor of applying the law” of Arizona. *Arlandson v. Hartz Mountain Corp.*, 792 F.Supp.2d 691, 709 (D.N.J.2011). Avram received and relied upon the Energy Star logo in Arizona, she purchased the refrigerator there, the refrigerator is located there, and performance of the contract occurred there. These factors outweigh the single fact that Samsung is located in New Jersey. *See, e.g.*, *Maniscalco v. Brother Int'l Corp.*, 793 F.Supp.2d 696, 707 (D.N.J.2011) (“Moreover, even if I were to find that BIC had made a decision to conceal in New Jersey, such a finding would not alter my determination that California and South Carolina have the most significant relationship to Plaintiffs' fraud claims; indeed, as discussed above, a majority of the courts in this district have determined that unlawful conduct emanating from New Jersey does not necessarily supersede the numerous contacts a plaintiff had with his home state.”); *Arlandson*, 792 F.Supp.2d at 709 (“The factual record is complete enough at this time to show that, accepting all of the facts as pleaded by Plaintiffs as true, the factors weigh in favor of applying the law of Plaintiffs' home states. Plaintiffs received and relied upon the alleged misrepresentations in their home states, the product is located in the Plaintiffs' home states, and the performance of the contract was rendered in Plaintiffs' home states. Balancing all these factors in favor of Plaintiffs' home states against the fact that Defendants' headquarters are located in New Jersey, the Court finds that the law of each Plaintiff's home state has the “most significant relationship” to Plaintiffs' consumer fraud action.”); *Cooper v. Samsung Elecs. Am., Inc.*, 374

Fed. App'x 250, 255 (3d Cir.2010) (noting at the motion to dismiss stage that a consumer fraud claim bears the most significant relationship with the state in which the product was “marketed, purchased, and used”); *Nikolin v. Samsung Elecs. Am., Inc.*, Civ. No. 10-1456, 2010 WL 4116997, at *3 (D.N.J. Oct.18, 2010) (finding at the motion to dismiss stage that the law of each plaintiffs home state has the most significant relationship, as “mere allegations that the unlawful conduct emanated from New Jersey did not outweigh the substantial ties to plaintiffs' home states”); *In re Philips/Magnavox TV Litig.*, Civ. No. 09-3072, 2010 WL 3522787, at *9-10 (D.N.J. Sept. 1, 2010) (analyzing the Section 148(2) factors at the motion to dismiss stage and finding that the law of each plaintiff's home state applies); *Warma Witter Kreisler, Inc. v. Samsung Elecs. Am., Inc.*, Civ. No. 08-5380, 2010 WL 1424014, at *1-2 (D.N.J. Apr. 8, 2010) (finding at motion to dismiss stage that allegation that product was designed in New Jersey “does not outweigh other, more significant, ties” to plaintiffs home state).

*19 Accordingly, the applicable law is that of Arizona. Of necessity, then, Avram's claim under the New Jersey Consumer Fraud Act is dismissed.

b. *Lark's MCPA Claim*

Samsung and Lowe's argue that Lark's MCPA cause of action must be dismissed because she does not allege reliance on any misrepresentation or actual loss.

i. *Choice of Law*

The parties agree that Maryland law applies to Lark's claim. I concur. There is a conflict between the NJCFA and the MCPA.

New Jersey's CFA does not require scienter as an element of proof with respect to affirmative acts by defendants, whereas the Maryland Consumer Protection Act (CPA) requires scienter. Further, actual conflicts exist regarding remedies. New Jersey's CFA entitles a successful claimant to treble damages plus attorney's fees and costs, whereas Maryland's CPA does not provide for treble damages and does not provide for mandatory attorney's fees, but allows for their award in the

court's discretion. It is thus abundantly clear that actual conflicts exist, thus requiring an analysis of the second prong.

Margulies v. Chase Manhattan Mortgage Corp., A-4087-03T3, 2005 WL 2923580 (N.J.Super.Ct.App.Div. Nov.7, 2005) (internal citations omitted).

Under that second prong, I must determine which state has the more significant relationship to the consumer fraud issue by examining the Restatement (Second) of Conflict of Laws factors that apply to fraud actions, found in Section 148. *Maniscalco v. Brother Int'l Corp. (USA)*, 793 F.Supp.2d 696, 704 (D.N.J.2011) *aff'd sub nom. Maniscalco v. Brother Int'l (USA) Corp.*, 709 F.3d 202 (3d Cir.2013) (quoting *P.V. v. Camp Jaycee*, 197 N.J. 132, 136, 962 A.2d 453 (2008)); *Agostino v. Quest Diagnostics Inc.*, 256 F.R.D. 437, 463-64 (D.N.J.2009). As with Avram, Section 148(1) does not apply because Lark's purchase and use of the refrigerator took place in Maryland, and the alleged false representations were made in New Jersey. Instead, I must look at the factors in Section 148(2).

On balance, these factors point to Maryland as having the most significant relationship to the claim at issue. The first two factors favor Maryland because Lark received and acted in reliance on the representation—the Energy Star logo—in Maryland. The last two factors also support Maryland because Lark purchased and used the refrigerator in Maryland. The third factor, the location where the representation was made, points to New Jersey. The fourth factor, the residence and place of incorporation and business of the parties, is balanced.

In these circumstances, ample case law establishes that the factors, both in number and weight, favor Maryland. See *Maniscalco*, 793 F.Supp.2d at 708 (“A majority of courts in this District have held that the mere fact that a company is headquartered in New Jersey will “not supersede the numerous contacts with the consumer's home state” for purposes of determining which state has the most significant relationship under Restatement § 148(2).”); *Cooper v. Samsung Electronics America, Inc.*, 374 Fed. App'x 250, 255 (3d Cir.2010) (upholding a District Court's refusal to apply the NJCFA where plaintiff, an Arizona resident, learned of, purchased and used a Samsung television in Arizona and where New Jersey's only connection to the matter was the fact that Samsung's headquarters were located

in New Jersey); *Nikolin v. Samsung Electronics America, Inc.*, Civ. No. 10-1456, 2010 WL 4116997, at *4 (D.N.J. Oct.18, 2010) (collecting cases and holding that even where a plaintiff has alleged that “unlawful conduct emanated from New Jersey,” such contact does not “outweigh the substantial ties to plaintiffs home states based on other factors under § 148(2).”); *Warma Witter Kreisler, Inc. v. Samsung Elecs. Am., Inc.*, Civ. No. 08-5380, 2010 WL 1424014, at *4 (D.N.J. Apr.8, 2010) (holding that an “allegation that [S]amsung designed the product's operation in New Jersey does not outweigh the other, more significant, ties to Illinois.”); *Knox v. Samsung Electronics America, Inc.*, Civ. No. 08-4308, 2009 WL 1810728, at *4 (D.N.J. June 25, 2009) (applying Georgia's consumer fraud law where “the consumer contacts ... all occurred in Georgia” and noting that despite Samsung's headquarters and the alleged wrongdoing occurring in New Jersey, “it is not clear ... that New Jersey intended out-of-state consumers to engage in end runs around local law in order to avail themselves of collective and class remedies that those states deny.”). I will apply the law of Maryland, the state with the more significant contacts.

ii. Analysis

*20 I therefore analyze Lark's claim against Lowe's under the Maryland Consumer Protection Act. The MCPA prohibits any “unfair or deceptive trade practice” in “[t]he sale ... of any consumer goods.” Md.Code Ann., Com. Law § 13-303(1). The MCPA defines “unfair or deceptive” trade practices to include “false ... or misleading oral or written statement[s] ... or other representations ... [that have] the capacity, tendency, or effect of deceiving or misleading consumers.” *Id.* § 13-301. Consumers “may bring an action to recover for injury or loss sustained ... as the result of” such a misrepresentation. *Id.* § 13-408(a).

A consumer bringing a private action under MCPA, § 13-408, must allege (1) an unfair or deceptive practice or misrepresentation that (2) was relied upon, and (3) caused actual injury. See *Lloyd v. Gen. Motors Corp.*, 397 Md. 108, 143, 916 A.2d 257, 277 (2007); *Philip Morris Inc. v. Angeletti*, 358 Md. 689, 752 A.2d 200, 235 (2000). “A consumer relies on a misrepresentation when the misrepresentation substantially induces the consumer's choice.” *Stewart v. Bierman*, 859 F.Supp.2d 754, 768-69 (D.Md.2012) (quoting *Bank of America v. Jill P. Mitchell Living Trust*, 822 F.Supp.2d 505, 532 (D.Md.2011)).

Lark's Complaint does not sufficiently allege that the Energy Star logo substantially induced her to purchase the

refrigerator. It does not say, for instance, that she decided to purchase the refrigerator because of its Energy Star qualification. Nor does it allege more generally that she had limited her search to Energy Star-qualified refrigerators. She asserts that, absent the Energy Star logo, she would not have purchased the refrigerator “on the same terms.” Because Lark's allegations of reliance are somewhat vague and conclusory, they “are not entitled to the assumption of truth.” *Bistrian v. Levi*, 696 F.3d 352, 365 (3d Cir.2012). I find that Lark's MCPA claim is inadequately pleaded and I will dismiss it.¹³

13

On the other hand, I reject Samsung and Lowe's argument that Lark failed to allege actual loss. “A complaint adequately pleads loss, for instance, when it points to some amount that it would ‘take to remedy the loss [the plaintiff] incurred as a result of the respondents' alleged deceptive trade practices.’” *Jones v. Koons Auto., Inc.*, 752 F.Supp.2d 670, 684 (D.Md.2010) (quoting *Lloyd*, 397 Md. at 150, 916 A.2d 257). Here, Lark has alleged that she paid a premium for the refrigerator and paid higher electricity bills because the refrigerator was not Energy Star-compliant. This suffices to survive a motion to dismiss. See *Dwoskin v. Bank of Am., N.A.*, 850 F.Supp.2d 557, 570 (D.Md.2012) (holding that actual loss prong of MCPA claim was properly alleged by plaintiffs' claim that they “suffered damages from paying a higher interest rate than they otherwise would have been charged.”).

F. Unjust Enrichment

Samsung and Lowe's have moved to dismiss Avram's and Lark's unjust enrichment claims because (1) unjust enrichment is superfluous based on the presence of other tort claims; (2) neither Avram nor Lark can allege that they expected to receive remuneration from Samsung or Lowe's; and (3) because Avram and Lark purchased the refrigerators from Lowe's, neither Plaintiff conferred a benefit directly on Samsung.

Unjust enrichment is a shared feature of many states' common law. For unjust enrichment claims, many courts have found that there is no actual conflict between different states' laws. See *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 58 (D.N.J.2009) (finding that any differences under the laws of the various states are “not material and do not create actual conflict”); *Agostino v. Quest Diagnostics*

Inc., 256 F.R.D. 437, 464 (D.N.J.2009) (concluding that “there are no actual conflicts among the laws of unjust enrichment”); *Powers v. Lycoming Engines*, 245 F.R.D. 226, 231 (E.D.Pa.2007) (examining the unjust enrichment laws of the 50 states and concluding that, “[a]lthough there are numerous permutations of the elements of the cause of action in the various states, there are few real differences”). I see no significant conflicts between the unjust enrichment law of New Jersey, Arizona, North Carolina, and Maryland.¹⁴ Therefore, I will apply New Jersey law.

¹⁴ “[T]o claim unjust enrichment” under New Jersey law, “a plaintiff must allege that (1) at plaintiffs expense (2) defendant received benefit (3) under circumstances that would make it unjust for defendant to retain benefit without paying for it.” *Snyder v. Farnam Companies, Inc.*, 792 F.Supp.2d 712, 723–24 (D.N.J.2011).

“A claim of unjust enrichment under Arizona law has five elements: ‘(1) an enrichment, (2) an impoverishment, (3) a connection between the enrichment and impoverishment, (4) the absence of justification for the enrichment and impoverishment, and (5) the absence of a remedy provided by law.’ ” *R. Prasad Indus. v. Flat Irons Envtl. Solutions Corp.*, Civ. No. 12–8261, 2013 WL 2217831, at *12 (D.Ariz. May 20, 2013) (quoting *Freeman v. Sorchych*, 226 Ariz. 242, 251, 245 P.3d 927, 936 (Ct.App.2011)); *see also Cooper v. Samsung Electronics Am., Inc.*, Civ. No. 07–3853, 2008 WL 4513924, at *9 (D.N.J. Sept. 30, 2008) (applying New Jersey law after finding no conflict between unjust enrichment law of Arizona and New Jersey).

“The Court of Appeals of Maryland has defined unjust enrichment as constituting three elements:

- ‘1. A benefit conferred upon the defendant by the plaintiff;
2. An appreciation or knowledge by the defendant of the benefit; and
- ‘3. The acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without the payment of its value.’ ”

Sensormatic Sec. Corp. v. Sensormatic Electronics Corp., 249 F.Supp.2d 703, 708 (D.Md.2003) (quoting *County Comm’rs v. J. Roland Dashiell & Sons, Inc.*, 358 Md. 83, 95 n. 7, 747 A.2d 600, 607 n. 7 (2000)).

North Carolina law provides that “[i]n order to state a claim for unjust enrichment, the plaintiffs allegations must set forth that a benefit was conferred on the defendant, that the defendant accepted the benefit, and that the benefit was not gratuitous.” *Jackson v. Carolina Hardwood Co.*, 120 N.C.App. 870, 872, 463 S.E.2d 571, 573 (1995) (citing *Booe v. Shadrick*, 322 N.C. 567, 570, 369 S.E.2d 554, 556 (1988)).

*21 Avram and Lark allege that they each conferred an benefit on Samsung and Lowe’s by purchasing refrigerators that were not in fact Energy Star-compliant. (Avram Compl. ¶ 57; Lark Compl. ¶ 56). Samsung and Lowe’s collected these revenues for what was advertised as an Energy Star-qualified refrigerator, when, in fact, the refrigerators did not meet Energy Star requirements. (Avram Compl. ¶ 58; Lark Compl. ¶ 57). As a result, Plaintiffs paid a price premium for a product that did not deliver promised energy savings. (Avram Compl. ¶ 58; Lark Compl. ¶ 57). I believe the Complaints adequately allege each element of an unjust enrichment claim, with one exception.

The requirement that a plaintiff must confer a benefit on the defendant “has been interpreted by New Jersey courts as a requirement that ‘the plaintiff allege a sufficiently direct relationship with the defendant to support the claim.’ ” *Snyder v. Farnam Companies, Inc.*, 792 F.Supp.2d 712, 724 (D.N.J.2011) (quoting *Nelson v. Xacta 3000 Inc.*, Civ. No. 08–5426, 2009 WL 4119176, at *3 (D.N.J. Nov.24, 2009) (citing *Maniscalco v. Brother Int’l Corp.*, 627 F.Supp.2d 494, 505–06 (D.N.J.2009)); *see also Cooper v. Samsung Elec.*, Civ. No. 07–3853, 2008 WL 4513924, at *10 (D.N.J. Sept. 29, 2008) (dismissing an unjust enrichment claim where consumer’s purchase was through a retailer, as there was no relationship conferring any direct benefit on the manufacturer). “When consumers purchase a product from a third party, they confer a benefit on that third party, not on the manufacturer.” *Snyder*, 792 F.Supp.2d at 724 (citing cases).

Avram and Lark purchased the refrigerators from Lowe’s, not Samsung. Therefore, they did not confer a sufficiently direct benefit on Samsung. Accordingly, their unjust enrichment claims against Samsung must be dismissed.¹⁵

¹⁵ Avram and Lark note that a similar unjust enrichment claim in *Palmeri v. LG Electronics USA, Inc.*, another consumer products suit, was not dismissed. Civ. No. 07–5706, 2008 WL 2945985

(D.N.J. July 30, 2008). In that case, the defendants did not make, nor did the court address, the argument that the plaintiff-purchaser did not confer a benefit on the manufacturer, as opposed to the retailer, giving it little force here.

The claims against Lowe's, however, will remain. It is true that unjust enrichment often turns out to be superfluous in light of other causes of action—*i.e.*, that it is only a contractual breach or the commission of a tort that makes the enrichment “unjust.” Nevertheless, to dismiss the claim on that basis would be premature at this point.¹⁶ Lowe's motion to dismiss this count is denied.

¹⁶ I say “at this point” because a motion to dismiss is directed to plaintiffs pleading, and the unjust enrichment claim is pleaded in the alternative, as the federal rules permit. *Fed.R.Civ.P. 8(d)(2)* (“A party may set out two or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones.”). *See Palmieri, 2008 WL 2945985 at *7* (“unjust enrichment is, by its nature, an alternative remedy to contract and tort remedies....It is inherent

in a claim for unjust enrichment that it is pled in the alternative to a claim for recovery on the contract.”).

IV. CONCLUSION

For the reasons stated above, Samsung and Lowe's Motions to Dismiss are **GRANTED IN PART** and **DENIED IN PART**. Specifically the Motions to Dismiss are

1. **GRANTED** as to (1) Avram's cause of action against Samsung for breach of the implied warranty of merchantability; (2) Avram's and Lark's claims under the NJCFA and MCPA, respectively; and (3) Avram's and Lark's unjust enrichment claims against Samsung only.
2. **DENIED** as to all remaining claims in both Complaints.

An appropriate order follows.

All Citations

Not Reported in F.Supp.2d, 2013 WL 3654090, 81 UCC Rep.Serv.2d 48

TAB 5

2015 WL 268857

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Deborah A. BECKER and
Raymond Becker, Plaintiffs,

v.

SMITH & NEPHEW, INC., ABC Corp. I-X,
John Doe I-X, and Jane Doe I-X (said names
being fictitious and unknown), Defendants.

Civ. No. 14-5452 (WHW)(CLW).

Signed Jan. 20, 2015.

Attorneys and Law Firms

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Defendants.

OPINION

WALLS, Senior District Judge.

*1 Plaintiffs Deborah Becker and Raymond Becker bring this products liability case, involving a [hip implant](#), against Defendant Smith & Nephew, Inc. Defendant removed the case from New Jersey Superior Court and now moves to dismiss. Defendant argues that the complaint's allegations are too vague to meet federal pleading standards, and that New Jersey law bars several causes of action. Decided without oral argument under [Fed.R.Civ.P. 78](#), Defendant's motion is granted. Plaintiffs are granted leave to file an amended complaint within 90 days from the date of this Opinion.

BACKGROUND

Plaintiffs filed a complaint in New Jersey Superior Court on May 20, 2014. ECF No. 1-1. The factual allegations of the complaint are that "Defendants, Smith & Nephew, Inc. and/or ABC Corp. I-X ... owned, designed, manufactured, assembled, packaged, repaired, modified, marketed, sold and/or distributed or otherwise placed in the stream of commerce

a certain product more particularly known as a [hip implant](#)." Compl. ¶ 1. "On or about June 1, 2012, the Smith & Nephew, Inc. [hip implant](#) was voluntarily recalled." *Id.* ¶ 3. "Plaintiff, Deborah A. Becker, only received notification of the voluntary recall on or about April 2013." *Id.* ¶ 4. "On or about August 16, 2007, plaintiff, Deborah A. Becker, underwent [hip surgery](#) at which time a Nephew & Smith, Inc. [sic] [hip implant](#) was implanted." *Id.* ¶ 5. "On or about September 6, 2013, plaintiff, Deborah A. Becker, was caused to undergo surgery to remove and replace the defective Smith & Nephew, Inc. [hip implant](#) as blood work results revealed high levels of cobalt toxicity in her system ..." *Id.* ¶ 6. The [hip implant](#) caused Deborah Becker to suffer injuries. *Id.* ¶ 7.

The complaint lists six counts. Though none of the headings is expressly labeled with a cause of action, the Court interprets the complaint as sounding in negligence (First Count), loss of consortium (Second Count), strict liability under the New Jersey Products Liability Act (Third Count), breach of express and/or implied warranties (Fourth Count), failure to warn (Fifth Count), and punitive damages (Sixth Count).

Defendant removed the action to this Court on August 29, 2014, ECF No. 1, and now moves to dismiss. ECF No. 4. Defendant argues that the complaint does not allege facts sufficient to support the products liability and breach of express warranty claims; that the New Jersey Products Liability Act bars the claims for negligence, breach of implied warranty, and common law failure to warn; and that the claims for loss of consortium and punitive damages are derivative and must be dismissed along with the others.

Plaintiffs did not timely respond to the motion. On December 3, 2014, after their response to the motion was due, Plaintiffs mailed the Court a short letter asking the Court to deny the motion. Citing no case or other authority, the letter attached what it alleged were medical records of Deborah Becker and an earlier letter from Plaintiffs' counsel to Defendant's counsel describing those records. Plaintiffs later filed the letter and attachments on ECF. ECF No. 9.

STANDARD OF REVIEW

*2 Under [Federal Rule of Civil Procedure 8\(a\)\(2\)](#), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." [Fed.R.Civ.P. 8\(a\)\(2\)](#). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, 'to state

a claim to relief that is plausible on its face.’ “ *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). A claim is plausible on its face “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* “A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement.” *Id.* (internal quotations and alterations omitted). “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘shown’—that the pleader is entitled to relief.” *Id.* at 679.

DISCUSSION

The New Jersey Products Liability Act Does Not Permit Plaintiffs' Causes of Action for Negligence and Breach of Implied Warranty

The New Jersey Product Liability Act, [N.J.S.A. 2A:58C-1](#) to [-11](#) (“PLA”) is the exclusive remedy for personal injury claims arising out of product use. *See, e.g., Koruba v. American Honda Motor Co., Inc.*, 396 N.J.Super. 517, 935 A.2d 787, 795 (N.J.App.Div.2007). The PLA “governs any claim or action for harm caused by a product, irrespective of the theory underlying the claim, except actions for breach of an express warranty.” *Id.* (citing [N.J.S.A. 2A:58C-1\(b\)](#) (3) and cases). The PLA “no longer recognizes negligence or breach of warranty (with the exception of an express warranty) as a viable separate claim for harm, including personal injury, caused by a defective product or an inadequate warning.” *Id.*; *see also Fidelity and Guar. Ins. Underwriters, Inc. v. Omega Flex, Inc.*, 936 F.Supp.2d 441, 447 (D.N.J.2013). Plaintiffs' causes of action for negligence and breach of implied warranty must be dismissed.

The Complaint Does Not State Sufficient Facts to Support a Claim under the PLA

The PLA adopts a strict liability standard that focuses on “the actual condition of the product” rather than on the reasonableness of the manufacturer's conduct. *Coffman v. Keene Corp.*, 133 N.J. 581, 628 A.2d 710 (N.J.1993). In order to state a claim for strict liability under the PLA, a plaintiff must demonstrate that “the product was not reasonably fit, suitable or safe for its intended purpose because it either

contained a manufacturing defect, failed to contain adequate warnings or instructions, or was designed in a defective manner.” *Koruba*, 935 A.2d at 795, citing [N.J.S.A. 2A:58C-2](#); *see also Cornett v. Johnson & Johnson*, 414 N.J.Super. 365, 998 A.2d 543, 561–62 (N.J.App.Div.2010) *aff'd as modified*, 211 N.J. 362, 48 A.3d 1041 (N.J.2012). A product liability claim requires proof that (1) the product was defective, (2) the defect existed when the product left the manufacturer's control, (3) the defect proximately caused injuries to the plaintiff, and (4) the plaintiff was a reasonably foreseeable or intended user. *Sinclair v. Merck & Co.*, 195 N.J. 51, 948 A.2d 587, 595 (N.J.2008) (citing *Myrlak v. Port Auth. of N.Y. & N.J.*, 157 N.J. 84, 723 A.2d 45 (N.J.1999)). “The mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect.” *Myrlak*, 723 A.2d at 52 (citation omitted).

*3 The barebones factual allegations of the present complaint are insufficient to support any theory under the PLA.

Manufacturing Defect

A manufacturing defect is a deviation “from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae.” [N.J.S.A. 2A:58C-2a](#); *see also Myrlak*, 723 A.2d at 51.

Plaintiffs do not allege facts to indicate that this particular implant deviated from the manufacturer's specifications or otherwise identical units. The complaint does not allege that a defect existed when the product left the manufacturer's control, specify how the defect proximately caused injuries to Deborah Becker, or identify her as a reasonably foreseeable end user of this particular device. The specific name of the implant does not appear in the complaint, nor does the medical condition which it was intended to treat. Though alleging “high levels of cobalt toxicity in [Deborah Becker's] system,” the complaint does not allege that the product was the proximate cause of this condition, or that the high levels caused a specific injury. Compl. ¶ 6. Apart from labeling the product a “Smith & Nephew hip implant,” Plaintiffs do not expressly identify Defendant's relationship to the product or role in the chain of commerce, vaguely stating that either Smith & Nephew or a fictitious defendant did one of a number of activities, including and potentially limited to “own[ing]” or “packag[ing]” the product. *Id.* ¶¶ 1–2.

Design Defect

A design defect is something that renders a product not reasonably fit, suitable or safe for its intended purpose. *N.J.S.A. 2A:58C-2*; see *Paredes v. Ford Motor Co.*, 2008 WL 5156473, at *4 (N.J.App.Div.2008). The PLA further defines a design defect as a danger inherent in a product that has been manufactured as intended, when that danger, as a public policy matter, is greater than can be justified by the product's utility. *Id.* To evaluate whether the design was defective, New Jersey courts perform a risk-utility analysis that considers seven factors:

1. The usefulness and desirability of the product—its utility to the user and to the public as a whole.
2. The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
3. The availability of a substitute product that would meet the need and not be as unsafe.
4. The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
5. The user's ability to avoid danger by the exercise of care in the use of the product.
6. The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product or of the existence of suitable warnings or instructions.
- *4 7. The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

See *Sampson v. Glock, Inc.*, 2014 WL 1225581, at *2–3 (D.N.J.2014) (citing *Johansen v. Makita U.S.A., Inc.*, 128 N.J. 86, 607 A.2d 637, 642–43 (N.J.1992)).

The complaint contains no factual allegations that would satisfy these elements. It neither addresses the seven factors above nor specifies a defect in the product's design. As with a manufacturing defect theory, a design defect theory cannot be maintained without allegations that the defect existed when the product left the manufacturer's control, the particular defect was the proximate cause of injuries to Deborah Becker, and Deborah Becker was a reasonably foreseeable or intended user.

Failure to Warn¹

¹ The Court interprets Plaintiffs' Fifth Count for failure to warn as arising under the PLA, rather than common law. Absent a "contractual obligation to warn" that is "materially more rigorous than the duty imposed by statute or when a person other than the manufacturer or seller of the product assumes a duty to warn," the PLA subsumes common law claims for failure to warn. See *Recola v. Morbark Industries, Inc.*, 934 F.2d 483, 489–94 (3d Cir.1991) (interpreting N.J.S.A. § 2A:58C-1(b) (2)).

"A plaintiff asserting a cause of action based on failure to warn must establish all the same elements required for an action based on a defective product." *London v. Lederle Labs.*, 290 N.J.Super. 318, 675 A.2d 1133 (App.Div.1996), *aff'd as modified by Batson v. Lederle Labs.*, 152 N.J. 14, 702 A.2d 471 (N.J.1997). In a failure to warn claim, "the defect is the absence of a warning to unsuspecting users that the product can potentially cause injury." *Toms v. J.C. Penney Co.*, 304 F. App'x 121, 126 (3d Cir.2008) (citing *Coffman v. Keene Corp.*, 133 N.J. 581, 628 A.2d 710, 716 (N.J.1993)). The manufacturer has a duty to warn of "dangers" that it knew, or that it "should have known on the basis of reasonably obtainable or available knowledge." *Feldman v. Lederle Labs.*, 97 N.J. 429, 479 A.2d 374 (N.J.1984). It satisfies that duty by giving "an adequate warning or instruction." N.J.S.A. 2A:58C-4; see *Cornett*, 414 N.J.Super. 365, 998 A.2d 543 at 563. The adequacy of the warning is determined in part by "taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used." N.J.S.A. § 2A:58C-4; *Port Auth. of N.Y. and N.J. v. Arcadian Corp.*, 189 F.3d 305, 319 (3d Cir.1999).

"[B]efore reaching the question of whether the product contained an adequate warning, plaintiff must first establish that there was a latent danger of which the manufacturer had a duty to warn." *Toms*, 304 F. App'x at 127 (citing *Mathews v. University Loft Co.*, 387 N.J.Super. 349, 903 A.2d 1120, 1125 (N.J.2006)). A manufacturer must have "sufficient knowledge to trigger the duty to provide a warning of the harmful effects of its product." *Toms*, 304 F. App'x at 127 (citing *James v. Bessemer Processing Co., Inc.*, 155 N.J. 279, 714 A.2d 898, 908 (N.J.1998)). There is no duty to warn if the danger is obvious. *Mathews*, 903 A.2d at 1128–29.

The complaint does not state specific facts regarding the alleged inadequate warning. There is no identification of

the latent danger, assertion that the danger is not obvious, or allegation that Defendant knew or should have known about it at a particular time. The complaint is silent as to whether Defendant gave a warning that did not reveal a particular danger, gave a warning that was untimely, or gave no warning at all. Plaintiffs do not assert that the inadequacy of the warning was the proximate cause of Deborah Becker's injuries. The complaint does not identify Deborah Becker as an intended user of the product, or state how the warning was inadequate in light of the ordinary knowledge common to intended users.

*5 As Plaintiffs do not plead facts sufficient to support a reasonable inference that Defendant is liable under any theory set forth in the PLA, the Third and Fifth Counts are dismissed.

Breach of Express Warranty

New Jersey law establishes three ways to create an express warranty:

- (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise;
- (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description;
- (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

N.J.S.A. § 12A:2-313; see also *Kuzian v. Electro lux Home Products, Inc.*, 937 F.Supp.2d 599, 612 (D.N.J.2013). Courts have dismissed claims for breach of an express warranty where plaintiffs fail to specify any factual support as to the specific language or source of the alleged warranty. See, e.g., *Schraeder v. Demilec (USA) LLC*, 2013 WL 3654093, at *6 (D.N.J.2013). "To prevail on a claim of breach of express warranty, a plaintiff must [also] show ... that the warranty was relied upon." See *Kuzian v. Electrolux Home Products, Inc.*, 937 F.Supp.2d 599, 617 (D.N.J.2013) (citations omitted).

Here the complaint contains no factual allegations regarding an express warranty. It mentions neither an affirmation of fact by the Defendant, nor a description of the goods, nor a sample or model which was the basis of a bargain. The complaint does not specify how the device did not function as warranted or how Plaintiffs relied on the warranty. This cause of action must be dismissed.

Loss of Consortium and Punitive Damages Are Derivative Claims

"Loss of consortium is a derivative claim which depends for its sustenance upon a viable tort claim of the spouse." *Finley v. NCR Corp.*, 964 F.Supp. 882, 889 (D.N.J.1996); see also *Banks v. International Rental and Leasing Corp.*, 680 F.3d 296, 300 n. 8 (3d Cir.2012). Likewise, there can be no claim for punitive damages in a products liability case where there is no viable underlying cause of action. See *Oliver v. Raymark Industries, Inc.*, 799 F.2d 95, 97-98 (3d Cir.1986) (citing Restatement (Second) of Torts § 908, comment c (1979) (in awarding punitive damages "[i]t is essential ... that facts be established that, apart from punitive damages, are sufficient to maintain a cause of action.")). Because all other causes of action are dismissed, Plaintiffs' claims for loss of consortium and punitive damages are dismissed as well.

Plaintiffs' Submissions in Response to this Motion Are Unavailing

Regarding the attachments Plaintiffs submitted with their letter of December 3, 2014, the Court first reminds Plaintiffs' counsel of Local Rule 7.1(b)(2), which requires that all papers in support or opposition to a motion be filed electronically. The Court not only rejects these materials as untimely and improperly submitted, but need not consider them in response to this motion. A court is generally confined to the four corners of the complaint when evaluating its sufficiency. See *Tri3 Enterprises, LLC v. Aetna, Inc.*, 535 F. App'x 192, 195 (3d Cir.2013). A trial court does have discretion to accept materials beyond the pleadings. See *In re Kiwi Intern. Air Lines, Inc.*, 344 F.3d 311, 315 n. 3 (3d Cir.2003). If a court accepts such materials, it must convert the motion into one for summary judgment. Fed.R.Civ.P. 12(d). With too much discovery required to properly evaluate a claim such as this one, the Court declines to convert the motion into one for summary judgment and declines to accept Plaintiffs' supplemental materials.

Plaintiffs Are Granted Leave to Amend

*6 Leave to amend a pleading “shall be freely given when justice so requires.” *Fed.R.Civ.P. 15(a)*; *see also Foman v. Davis*, 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed.2d 222 (1962). There has been no prior dismissal of the complaint, Plaintiffs have not previously amended their pleadings, and Defendant has not demonstrated that it would be prejudicial, futile, or otherwise unfair for Plaintiffs to be given leave to amend. Because the complaint was drafted as part of a state court filing, but is now subject to the higher pleading standards applicable in federal court,² it is consistent with principles of fairness and justice to afford Plaintiffs an opportunity to file an amended complaint within 90 days of the date of this Opinion.

² Compare New Jersey's pleading standard: “In considering a motion to dismiss under Rule 4:6–2(e), courts search the allegations of the pleading

in depth and with liberality to determine whether a cause of action is ‘suggested’ by the facts. They must ascertain whether the fundament of a cause of action may be gleaned even from an obscure statement of claim, opportunity being given to amend if necessary.” *Printing Mart–Morristown v. Sharp Electronics Corp.*, 116 N.J. 739, 563 A.2d 31, 34 (N.J.1989) (citations omitted).

CONCLUSION

Defendant's motion is granted. The complaint is dismissed without prejudice. Plaintiffs may file an amended complaint within 90 days of the date of this Opinion.

All Citations

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TAB 6

2018 WL 928237

Only the Westlaw citation is currently available.
United States District Court, W.D. Pennsylvania.

William L. BELL, Jr., Plaintiff,

v.

BOEHRINGER INGELHEIM

PHARMACEUTICALS, INC., Boehringer

Ingelheim Pharma GmbH & Co. KG,
Boehringer Ingelheim International GmbH,
and; and Eli Lilly & Company, Defendants.

CIVIL ACTION NO. 17-1153

Signed 02/15/2018

Attorneys and Law Firms

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MEMORANDUM OPINION

Joy Flowers Conti, Chief United States District Judge

I. Introduction

*1 Plaintiff William L. Bell, Jr. (“Bell”) alleges that he developed an acute kidney injury as a direct result of taking the prescription drug Jardiance. Bell alleges numerous claims under Pennsylvania law. This court has subject-matter jurisdiction based on diversity of citizenship.

Defendants Boehringer Ingelheim Pharmaceuticals, Inc. (“BIP”)¹ and Eli Lilly & Company (“Lilly”) filed a motion to dismiss all but counts 4 and 9 (ECF No. 10), arguing that Pennsylvania law broadly bars all non-negligence claims asserted against prescription drug manufacturers. Defendants also argue that the entire complaint should be dismissed for failing to comply with federal pleading standards. Lilly filed a separate motion to dismiss all claims against it (ECF No. 7), arguing that because BIP is the sole holder of the Jardiance New Drug Application (“NDA”) filed with the Food and Drug

Administration (“FDA”) Lilly never had authority to change Jardiance’s labeling or design. The motions are fully briefed and ripe for disposition. The parties agreed to stay the case pending the court’s resolution of these motions. (ECF No. 15).

1 Two other Boehringer entities named as defendants have not yet been served.

II. Factual Background

As set forth in the complaint, in July 2014, defendants submitted an NDA to the FDA for Jardiance. Complaint ¶ 20 (ECF No. 1). In August 2014, the FDA approved Jardiance for the treatment of Type II diabetes. *Id.* ¶ 21. Jardiance is the trademark for the drug empagliflozin, which is a member of the gliflozin class of sodium-glucose cotransporter 2 (“SGLT2”) inhibitors. *Id.* ¶ 22. SGLT2 inhibitors are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. *Id.* ¶ 24. Excess glucose is not metabolized. Instead, it is excreted through the kidneys. *Id.* ¶ 24. Jardiance is indicated for only improved glycemic control in type 2 adult diabetics, but defendants market it for off label purposes, including weight loss, reduced blood pressure and improved glycemic control in type 1 diabetes. *Id.* ¶ 25. Since the release of Jardiance, the FDA has received a significant number of reports of diabetic ketoacidosis. *Id.* ¶ 26. Bell alleges that defendants knew about the significant risk of diabetic ketoacidosis but did not adequately warn consumers or the medical community about the severity of such risks. *Id.* ¶ 30.

On June 13, 2015, Bell began taking Jardiance per his doctor’s instructions, primarily to treat diabetes. *Id.* ¶ 32. Bell relied on defendants’ claims that Jardiance was safe and effective for the treatment of diabetes. *Id.* ¶ 35. On August 31, 2015, Bell suffered acute renal failure. *Id.* ¶ 37. Bell does not plead any other facts about his medical condition.²

2 The complaint appears to be copied from another case with a female plaintiff, as there are multiple references to “her” and “she.” See, e.g., Complaint Introduction and ¶ 46.

The complaint asserts the following causes of action: (1) products liability—design defect (strict liability); (2) products liability—failure to warn (strict liability); (3) willful and wanton misconduct or gross negligence; (4) negligence; (5) breach of express warranty; (6) breach of implied warranty; (7) fraudulent misrepresentation; (8) negligent misrepresentation; (9) negligent design; (10) fraudulent concealment; and (11) fraud.

III. Standard of Review

*2 A motion to dismiss tests the legal sufficiency of the complaint. *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). In deciding a motion to dismiss, the court is not opining on whether the plaintiff will be likely to prevail on the merits; rather, when considering a motion to dismiss, the court accepts as true all well-pled factual allegations in the complaint and views them in a light most favorable to the plaintiff. *U.S. Express Lines Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002). While a complaint does not need detailed factual allegations to survive a Federal Rule of Civil Procedure 12(b)(6) (“Rule 12(b)(6)”) motion to dismiss, a complaint must provide more than labels and conclusions. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). A “formulaic recitation of the elements of a cause of action will not do.” *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986)). “Factual allegations must be enough to raise a right to relief above the speculative level” and “sufficient to state a claim for relief that is plausible on its face.” *Id.* “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. at 556, 127 S.Ct. 1955).

The plausibility standard is not akin to a “probability requirement,” but it asks for more than a sheer possibility that a defendant has acted unlawfully.... Where a complaint pleads facts that are “merely consistent with” a defendant’s liability, it “stops short of the line between possibility and plausibility of ‘entitlement to relief.’ ”

Id. (quoting *Twombly*, 550 U.S. at 556, 127 S.Ct. 1955) (internal citations omitted).

Two working principles underlie *Twombly*. *Id.* First, with respect to mere conclusory statements, a court need not accept as true all of the allegations contained in a complaint. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* (citing *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955.) Second, to survive a motion to dismiss, a claim must state a plausible claim for relief. *Id.* at 679, 129 S.Ct. 1937. “Determining whether a complaint states a plausible claim for relief will ... be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.* (citing 490 F.3d at 157-58). “But where the well-pled

facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]—that the pleader is entitled to relief.’ ” *Id.* (quoting Fed. R. Civ. P. 8(a)(2)). A court considering a motion to dismiss may begin by identifying pleadings that are not entitled to the assumption of truth because they are mere conclusions.

While legal conclusions can provide the framework of the complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

Id.

IV. Legal Analysis

A. Pennsylvania Law Regarding Claims Against Manufacturers of Prescription Drugs

This case is governed by Pennsylvania law. Defendants argue that under Pennsylvania law, product liability claims against pharmaceutical manufacturers can only be brought under a negligence theory.

1. Strict liability claims

In *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 889-90 (Pa. 1996), the Pennsylvania Supreme Court held that “where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer’s negligence, is the only recognized basis of liability.” *Id.* at 890 (emphasis added). The Pennsylvania Supreme Court explained in *Hahn* that the *Restatement (Second) of Torts* § 402A, comment k “denies application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings.” *Id.* For example, the *rabies vaccine* commonly leads to serious consequences when injected, but because the

disease itself leads to death, the marketing and use of the vaccine is fully justified. *Id.* at 890 n.2. That kind of product, properly prepared and accompanied by proper directions and warning, is not defective and is not unreasonably dangerous. *Id.*

*3 Bell argues that *Hahn* is “antiquated” and this court should instead follow the principles set forth in *Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 104 A.3d 328 (Pa. 2014), a case involving stainless steel tubing. *Tincher* did not address pharmaceutical drugs and did not overrule *Hahn*. See *id.* at 382 (recognizing that under *Hahn*, a manufacturer is immune from strict liability defective design claims premised upon sale of prescription drugs without adequate warnings). In addition, Bell argues that this court should follow *Lance v. Wyeth*, 624 Pa. 231, 85 A.3d 434 (Pa. 2014), which recognized a negligent design defect claim against a prescription drug manufacturer. *Lance* described *Hahn* as having a “truncated analysis” that offered a “poor foundation for extrapolation.” *Id.* at 452 n.21. The court emphasized in *Lance*, though, “that we are not revisiting *Hahn*.” *Id.* The court reiterated that “for policy reasons this Court has declined to extend strict liability into the prescription drug arena....” *Id.* at 264.

With respect to state law claims, this court is bound by the law as set forth by the Pennsylvania Supreme Court. *Hahn* is still good law and is controlling on cases involving prescription drugs. In *Hahn*, the supreme court rejected strict liability theories in the prescription drug context. Bell’s strict liability claims in counts 1 and 2 of the complaint must be dismissed.

2. Breach of warranty claims

In *Hahn*, the Pennsylvania Supreme Court did not specifically address breach of warranty claims. Its holding that negligence is the “only” recognized basis of liability, *id.* at 890, similarly precludes a claim against a prescription drug manufacturer based on an alleged breach of warranty. In *Salvio v. Amgen, Inc.*, 810 F.Supp.2d 745 (W.D. Pa. 2011), the court explained:

Pennsylvania state and federal courts have interpreted *Hahn* broadly to bar all non-negligence based claims asserted against a manufacturer of prescription drugs. *Leonard v. Taro Pharmaceuticals USA, Inc.*, No. 10-1241, 2010 WL 4961647, at *5,

2010 U.S. Dist. LEXIS 127892 (W.D. Pa. Dec. 2, 2010) (citing *Aaron v. Wyeth*, No. 07-927, 2010 WL 653984, at *11, 2010 U.S. Dist. LEXIS 14581, *30-1 (W.D. Pa. Feb. 19, 2010) (dismissing breach of express and implied warranty claims under *Hahn*); *Kline v. Pfizer, Inc.*, No. 08-3238, 2008 WL 4787577, at *3, 2008 U.S. Dist. LEXIS 101655, *7 (E.D. Pa. Oct. 31, 2008) (dismissing breach of express and implied warranty claims under *Hahn*); *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514, 548 (E.D. Pa. 2006) (dismissing breach of implied warranty claim under *Hahn*)).

Salvio, 810 F. Supp.2d at, 755-56; accord *Rowland v. Novartis Pharmaceuticals Corp.*, 34 F.Supp.3d 556, 568-69 (W.D. Pa. 2014). Bell’s claims for breach of express and implied warranties in counts 5 and 6 of the complaint will be dismissed.

3. Fraud claims

Counts 7, 10 and 11 of Bell’s complaint allege that defendants knowingly represented that Jardiance was safer than alternative medications and failed to make truthful representations regarding the risks of taking Jardiance. The case law is split regarding claims for fraudulent misrepresentation, fraudulent concealment and fraud.

Some courts hold that *Hahn* broadly bars all non-negligence based claims asserted against a manufacturer of prescription drugs. In *Leonard v. Taro Pharm. USA, Inc.*, No. 10CV1341, 2010 WL 4961647 (W.D. Pa. Dec. 2, 2010), the court reasoned that a claim of intentional misrepresentation or fraud is “a non-negligence based claim akin to strict liability for failure to warn, and is barred by *Hahn* and its progeny.” *Id.* at *5. Other courts have recognized fraud-based claims. In *Tatum v. Takeda Pharm. N. Am., Inc.*, No. CIV.A. 12-1114, 2012 WL 5182895 (E.D. Pa. Oct. 19, 2012), the court pointed out that *Hahn* required a seller of prescription drugs to warn not only of risks of which he reasonably should have knowledge, but also warn of risks of which he did, in fact, have knowledge. *Id.* at *4; see *Hahn*, 673 A.2d at 890 (a seller must warn of risks of which he “has

or reasonably should have knowledge") (emphasis added). *Accord Cutruzzula v. Bayer Healthcare Pharm. Inc.*, No. CV 14-1474, 2015 WL 8488670, at *5 (W.D. Pa. Nov. 17, 2015), report and recommendation adopted, No. CV 14-1474, 2015 WL 8492767 (W.D. Pa. Dec. 10, 2015) (refusing to dismiss fraud claims if they contain allegations of affirmative misrepresentations that go beyond a mere failure to warn).

*4 The court is persuaded that Pennsylvania law recognizes a cause of action for fraudulent marketing of prescription drugs. *Hahn* does not preclude claims where the plaintiff alleges that the seller had actual knowledge of the risks of prescription drugs and intentionally concealed them. The fraud claims in counts 7, 10 and 11 of Bell's complaint are not barred by *Hahn* as a matter of law.³

³ As will be discussed below, fraud claims are subject to rigorous pleading standards.

4. Negligent misrepresentation claim

Count 8 of Bell's complaint alleges negligent misrepresentation. Although the court in *Leonard* dismissed a fraudulent misrepresentation claim, it held that a claim for negligent misrepresentation is not barred by *Hahn*. 2010 WL 4961647, at *5 (quoting *Colacicco*, 432 F.Supp.2d at 548). This court agrees with that analysis. Because count 8 of Bell's complaint sounds in negligence, it is not barred by *Hahn*.

5. Gross negligence claim

In count 3 of the complaint, Bell alleges that defendants acted with willful and wanton conduct or gross negligence and seeks punitive damages. “[T]here is no separate cause of action under Pennsylvania law for gross negligence.” *Spence v. ESAB Group, Inc.*, 623 F.3d 212, 215 n. 2 (3d Cir. 2010) (citing *Hunter v. Squirrel Hill Assocs., LP*, 413 F.Supp.2d 517, 520 n. 2 (E.D. Pa. 2005) (“While Pennsylvania courts acknowledge differing standards of care, they do not recognize degrees of negligence as separate causes of action.”)). *See also Floyd v. Brown & Williamson Tobacco Corp.*, 159 F.Supp.2d 823, 828 (E.D. Pa. 2001) (dismissing plaintiff's separately pleaded claim for gross negligence); *Salvio*, 810 F.Supp.2d at 756 (same); *Kline v. Pfizer, Inc.*, No. CIV.A.08-3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008) (same).

The dismissal of a stand-alone gross negligence claim does not preclude Bell from pursuing damages (including punitive damages) if he is able to demonstrate that defendants were grossly negligent. As explained in *Daly v. New Century Trans, Inc.*, No. 1:11-CV-2037, 2012 WL 4060687 (M.D. Pa. Sept. 14, 2012):

Although not recognized as a separate cause of action, gross negligence has been recognized by Pennsylvania and federal courts interpreting Pennsylvania law as “a form of negligence where the facts support substantially more than ordinary carelessness, inadvertence, laxity, or indifference.” Thus, Pennsylvania law acknowledges differing standards of care, but does not recognize degrees of negligence as separate causes of action.

Id. at *4 (citations omitted) (recognizing that allegations of gross negligence could support a claim for punitive damages). In count 4, Bell asserts a claim of negligence which is sufficient to encompass gross negligence. In accordance with these standards, Count 3 of Bell's complaint will be dismissed as a separate cause of action because it is subsumed within the negligence claims.

In summary, counts 1, 2, 3, 5 and 6 of Bell's complaint are not recognized by controlling Pennsylvania law. Counts 1, 2, 5 and 6 will be dismissed with prejudice, without leave to amend. *Salvio*, 810 F.Supp.2d at 757 (denying leave to amend non-negligence claims as futile). Count 3 is being dismissed but it is not dismissed on the merits; it is dismissed because it is not a separate claim.

B. Federal Pleading Standards

Defendants contend that even if some of the claims asserted by Bell are theoretically cognizable, the complaint in this case fails to allege sufficient facts to make any claim plausible. Defendants, therefore, seek dismissal of the entire complaint.

*5 Bell argues that the claims are sufficiently pled. For example, Bell points to allegations that Jardiance was more dangerous than other risks associated with treatment of diabetes (although factual details are not provided), the benefits of Jardiance were outweighed by the risks, there are other (unspecified) design alternatives that have a better safety profile (although what those designs are, and how the safety profile is better are not pled), and Jardiance was more dangerous than the expectations of ordinary consumers and physicians (again, with no factual details provided).

Factual details are almost entirely lacking. The complaint appears to be copied from another source, because it refers to “her” and “she.” *See supra* note 2. There are no factual details about when Bell contracted diabetes, whether he has type I or type II [diabetes](#), whether he has other medical conditions, who his treating physicians were, why he decided to take Jardiance, what alternatives to Jardiance were discussed, whether he read the warnings, how long he took Jardiance or at what dose or why he believes his [acute renal failure](#) was caused by Jardiance.

A close examination of the complaint reveals that the vast majority of its averments are bald legal conclusions or a formulaic repackaging of the elements of the claim. Bell did not plead the roles of each defendant. Bell did not plead how each defendant’s conduct in the design of Jardiance, how warnings about Jardiance fell below the required standard of care or how each defendant’s alleged breaches of duty caused Bell’s injury. Bell did not explain how and why the design or warnings were defective. In paragraphs 22-24 of the complaint, Bell describes how SGLT2 inhibitors like Jardiance work. The complaint does not plead any facts, however, about why this design is defective. Bell conclusorily alleged that “several alternative safer products” exist (Complaint ¶ 29) but did not identify those products or explain why they are safer.

In *House v. Bristol-Myers Squibb Co.*, No. 3:15-894, 2017 WL 55876 (W.D. Ky. Jan. 4, 2017), and *Fleming v. Janssen Pharmaceuticals, Inc.*, 186 F.Supp.3d 826, 835 (W.D. Tenn. 2016), the courts dismissed very similar complaints asserting products liability claims against manufacturers of similar drugs for failing to plead sufficient facts. In *Fleming*, the court explained:

The only assertion as to how the product design was defective is a description of how the class of products works. (See Compl. ¶ 24 (“SGLT2 inhibitors ... are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for [kidney disease](#).”).) The Court cannot reasonably infer from the generic description of SGLT2 inhibitors’ mechanism of action that Invokana was defective or unreasonably dangerous. The facts are also insufficient as to the alleged defect as the cause of Plaintiff’s injuries. Plaintiff asserts, for example, that “[a]s a direct and proximate result of Defendants’ negligence, wrongful

conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Plaintiff suffered severe and permanent physical and emotional injuries.” (Compl. ¶ 48.) Under [Rule 12\(b\)\(6\)](#), such “unadorned, the-defendant-unlawfully-harmed-me accusation[s]” are insufficient to state a claim.

186 F.Supp.3d at 835-36. The court dismissed the failure to warn claim because the plaintiff failed to allege facts showing that the drug was unreasonably dangerous. *Id.* at 836.

*6 In *House*, the court similarly concluded that it could not infer defectiveness from a generic description of how SGLT2 inhibitors work. *House*, 2017 WL 55876 at *4. The court characterized the following allegations as formulaic legal conclusions that were insufficient to meet the *Twombly-Iqbal* standard: (a) the drugs “contained unreasonably dangerous design defects and were not reasonably safe as intended to be used”; (b) the drugs “were defective in design and formulation, making use of the drugs more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of diabetes”; (c) defendants “could have designed their respective [drugs] to make them less dangerous”; and (d) there “was a practical, technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing” the function of the drugs. *Id.* at *3-4. The court dismissed the failure to warn claim as similarly based on only conclusory statements. *Id.* at *4.

The allegations in Bell’s complaint are substantially identical to those held to be insufficient in *Fleming* and *House*. See *Salvio*, 810 F. Supp.2d at 754 (describing complaint as “little more than a list of legal conclusions regarding Defendants’ failure to test, market, warn, design, and manufacture”). There are simply no actual facts pled about how each defendant was negligent in Jardiance’s design or warnings or how each defendant’s alleged breaches of the standard of care caused Bell’s injuries. Bell’s complaint will likewise be dismissed.

Fraud claims are subject to the more rigorous standards of [Federal Rule of Civil Procedure 9\(b\)](#) and must be pled with particularity. See *House*, 2017 WL 55876 at *8 (dismissing fraud-based claims described at a high level of generality). The fraud-based claims in counts 7, 10 and 11 of Bell’s complaint fall far short of the [Rule 9](#) standard and must be dismissed.

In sum, the complaint fails to plead sufficient facts to make any claim “plausible,” as required by the Federal Rules of

Civil Procedure. The complaint, therefore, will be dismissed in its entirety.

C. Federal Preemption

Lilly filed a separate motion to dismiss, arguing that because BIPI is the sole holder of the NDA, Lilly had no ability to change Jardiance's label or design. Lilly reasons that because federal law required it to follow the NDA, Bell's contrary state law claims are preempted.

Lilly cites *Warren v. Boehringer Ingelheim Pharmaceuticals, Inc.*, No. 16-1326, 2017 WL 3970666 (S.D. Ind. Sept. 8, 2017) (involving Jardiance), and *Germain v. Teva Pharmaceuticals, USA, Inc.*, 756 F.3d 917 (6th Cir. 2014), which concluded that a manufacturer who does not hold the NDA has no ability to change the warning label or the design of the drug. In *Warren*, the court held that Lilly could not comply with any duty imposed by state law to change the design or labeling of Jardiance, and therefore, state law claims against Lilly were preempted. *Warren*, 2017 WL 3970666 at *16. Accord *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015) (a "post-approval design defect claim is clearly preempted by federal law").

Bell, in response, explains that his "claims focus on the initial design of Jardiance **prior to** FDA approval." ECF No. 17 at 5 (emphasis added); see ECF No. 17 at 6 ("Plaintiff's claims are premised on Eli Lilly's duty to initially design a reasonably safe product."). Bell apparently recognizes that he cannot pursue post-FDA approval claims against Lilly.

The case law regarding preemption of pre-approval design claims is not fully developed. Impossibility preemption is a demanding defense on which defendants bear the burden of proof. *Wyeth v. Levine*, 555 U.S. 555, 573, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009). The United States Court of Appeals for the Third Circuit has not addressed preemption in the prescription drug context. *But see Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 702-03 (3d Cir. 2016) (holding at the summary judgment stage that federal law did not preempt a products liability claim in the aviation industry and discussing preemption principles in the "analogous preapproval scheme for pharmaceutical labeling"). In *Warren*, the court refused to dismiss a claim against BIPI based on the original design of Jardiance before FDA approval. *Warren*, 2017 WL 3970666 at *10, 15. Accord *Estate of Cassel v. Alza Corp.*, No. 12-771, 2014 WL 856023 (W.D. Wis. Mar.

5, 2014) (holding that a pre-FDA approval design defect claim survived summary judgment because defendants failed to meet their burden to establish the preemption defense as a matter of law). In *Yates*, the court held that a pre-FDA approval design claim was preempted, but did so at the summary judgment stage, not on a motion to dismiss. 808 F.3d at 289, 299-300 (holding that the plaintiff's argument regarding a pre-approval duty to design a safer drug was "too attenuated"). The court recognized in *Yates*, however, that "[a]s a general matter, plaintiffs injured by brand-name prescription drugs retain state-law tort remedies against the manufacturer of those drugs, provided it is not impossible for the drug manufacturer to comply with both state and federal law." *Id.* at 294.

*7 As explained above, the complaint contains no factual details about Lilly's actions or how the design of Jardiance was allegedly defective prior to FDA approval. Without knowing what Lilly's actions were, the court cannot evaluate whether those actions create a conflict between Pennsylvania law and federal law. Given the lack of factual allegations in Bell's complaint and the unsettled state of preemption law, the court reserves ruling on the preemption issue at this time. Lilly's motion will be denied without prejudice.

V. Leave to Amend

Bell affirmatively requested leave to amend the complaint in the event that the motions to dismiss were granted. Pursuant to Rule 15, leave to amend should be freely granted. When a complaint is subject to dismissal under Rule 12(b)(6), district courts should generally permit an opportunity to amend unless an amendment would be inequitable, or otherwise unjust by way of futility, bad faith, or undue delay. *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006). There has been no undue delay.

As explained above, it is clear that Bell will be unable to correct the shortcomings identified in this opinion as to counts 1, 2, 5 and 6 because those claims are not recognized by controlling Pennsylvania law and as to count 3 because it is subsumed into the negligence claims. Leave to amend those claims is denied because amendment would be futile. Amendment of the negligence and fraud-based claims asserted by Bell in counts 4, 7, 8, 9, 10 and 11 is not necessarily futile. Those claims are being dismissed for failure to comply with the required pleading standards.

Bell may file an amended complaint on or before March 8, 2018. The court cautions that if Bell chooses to file an

amended complaint, it will be important for him to assure that the complaint contains all factual allegations needed to render the claims “plausible,” against each defendant, because the court is unlikely to permit a further “bite at the apple.” Bell must ensure that any fraud-based claims comply with the particularity standard in **Rule 9**. It will also be important for Bell to plead how the design or warnings were faulty. *See Salvio*, 810 F.Supp.2d at 750-51 (taking judicial notice of the package warning label); ECF No. 11 at 9 n.5 (purporting to quote from Jardiance’s warning label regarding **impaired renal function**).

VI. Conclusion

In accordance with the foregoing, Defendants' joint motion to dismiss (ECF No. 10) will be GRANTED, and Lilly's separate motion to dismiss (ECF No. 7) will be DENIED WITHOUT PREJUDICE. Counts 1, 2, 3, 5 and 6 are dismissed without leave to amend. Counts 4, 7, 8, 9, 10 and 11 are dismissed with leave to amend. An appropriate order will be entered.

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TAB 7

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Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Edna Diane BOWMAN and

Amy McHenry, Plaintiffs,

v.

RAM MEDICAL, INC., Amerimed Corp.,

Henry Schein, Inc., Marathon Medical

Corp., Medline Industries, MMS-A Medical

Supply Co., and Q-Med Corp., Defendants.

Civil Action No. 10-cv-4403 (DMC)(MF).

|

May 31, 2012.

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OPINION

DENNIS M. CAVANAUGH, District Judge.

*1 This matter comes before the Court upon the motion by Defendants RAM Medical, Inc., Henry Schein, Inc., Marathon Medical Corp., Medline Indus., MMS-A Medical Supply Co. and Q-Med Corp. (collectively, "Defendants") (ECF No. 34) to dismiss Plaintiff's complaint (ECF No. 1), filed on January 31, 2011. An amended motion to dismiss was filed by Defendants on September 30, 2011 (ECF No. 51). Defendant C.R. Bard, Inc. filed a motion to dismiss on April 23, 2012 (ECF No. 55). Pursuant to **FED.R.CIV.P. 78**, which states that the court has the authority to provide for submitting and determining the motions on briefs without oral hearings, no oral argument was heard.

I. BACKGROUND

A. Factual Background

Defendants are in the business of marketing, distributing, selling, manufacturing or causing to be manufactured the **surgical mesh** at issue in this litigation. (Pl.'s Compl. ¶ 35, Aug. 26, 2010, ECF No. 1). Defendants, at all relevant times, allegedly sold **surgical mesh** as sterile, Food and Drug Administration ("FDA") approved, indicated for surgical use and Bard-manufactured. *Id.* at ¶ 36. Plaintiffs bring this action on behalf of themselves and putatively on behalf all other similarly situated persons "in the United States who had Defendants' counterfeit **surgical mesh** surgically implanted from September 1, 2007 until the present." (Pl.'s Compl. ¶ 26). The Complaint includes specific information about two Plaintiffs, Edna Diane Bowman and Amy McHenry. On December 1, 2009, Plaintiff Edna Diane Bowman underwent a surgical procedure at Lexington Medical Center in West Columbia, South Carolina ("LMC"), during which Defendants' counterfeit mesh was implanted in her body. *Id.* at ¶ 40. On February 23, 2010, Plaintiff Amy McHenry underwent a laparoscopic **hernia** repair procedure at LMC, during which Defendants' counterfeit mesh was implanted in her abdomen. *Id.* at ¶ 37. On July 19, 2010, Plaintiff Bowman received a letter from LMC informing her that the **surgical mesh** implanted during her surgery was "counterfeit **surgical mesh**." *Id.* at ¶ 51. On July 15, 2010, Plaintiff McHenry received a letter from LMC informing her of the same. *Id.* at ¶ 49.

Essentially, Plaintiffs claim that a counterfeit product was used during surgery without their consent or knowledge. However, Plaintiffs cite no physical injury or harm resulting. Plaintiffs state their claims in five counts including: (1) violation of the New Jersey Consumer Fraud Act ("NJCFA"), (2) unjust enrichment and common law restitution, (3) breach of express warranty, (4) breach of implied warranty of merchantability and (5) breach of implied warranty of fitness for a particular purpose. Plaintiffs contend the nature of the action involves false, misleading, inaccurate, deceptive and unconscionable commercial practices. (Pl.'s Compl. ¶ 1).

Plaintiffs explain that their belief was that the **surgical mesh** implanted was: (1) Bard-manufactured, (2) sterile, (3) approved for use by the FDA, and (4) indicated for surgical use. (Pl.'s Compl. ¶ 47). Plaintiffs claim that in the condition in which Defendants sold their counterfeit mesh, the mesh had zero value. *Id.* at ¶ 48. Further, Plaintiffs state that had they

known that Defendants' surgical mesh was not as represented, they would not have purchased, or agreed to purchase of the surgical mesh for use during the surgical procedures. *Id.* at ¶ 54. The only ascertainable loss Plaintiffs allege is the purchase price of a product they believed to be something else. *Id.* at ¶ 55. Plaintiffs vaguely state they "will incur [future] costs to repair the damages caused by Defendants' unlawful activity," but omit to further explain such "repairs." *Id.*

*2 Plaintiffs seek relief that includes: class certification; declarations that Defendants' unlawful actions violate the NJCFA, breach express and implied warranties of merchantability and implied warranties of fitness, and unjustly enrich Defendants; orders directing disgorgement of profits derived from unlawful practices, compelling Defendants to reimburse Plaintiffs in an amount equal to their ascertainable loss, and treble damages pursuant to N.J.S.A. 56:8-1 et seq.; restitution; and, attorney's fees. (Pl.'s Compl. ¶ 93).

B. Procedural Background

This matter comes before the Court upon the motion by Defendants RAM Medical, Inc., Henry Schein, Inc., Marathon Medical Corp., Medline Indus., MMS-A Medical Supply Co. and Q-Med Corp. (collectively, "Defendants") (ECF No. 34) to dismiss Plaintiff's complaint (ECF No. 1), filed on January 31, 2011. An amended motion to dismiss was filed by Defendants on September 30, 2011 (ECF No. 51). This Court *sua sponte* consolidated the *Calo Action* (Docket No. 11-cv-7381) with this matter on April 17, 2012.

Defendant C.R. Bard, Inc. filed a motion to dismiss on April 23, 2012 (ECF No. 55).¹ Plaintiff Irene Kirk Calo then filed a motion to voluntarily dismiss her action, without prejudice, on May 21, 2012 (ECF No. 58), which this Court granted (ECF No. 58) pursuant to FED. R. CIV. P. 41(a)(2).

¹ Thereafter, Plaintiff Calo and C.R. Bard, Inc. stipulated to dismissal of Plaintiff's claims against C.R.Bard, Inc. with prejudice on May 29, 2012. Since Calo's motion for voluntary dismissal was granted on this day, this point is moot.

II. STANDARD OF REVIEW

In deciding a motion to dismiss, the District Court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most

favorable to [the Plaintiff]." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 228 (3d Cir.2008) The Plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). "[A court is] not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986). Instead, when their truth is assumed, those factual allegations "must be enough to raise a right to relief above a speculative level." *Twombly*, 550 U.S. at 555. Plaintiff's obligation "requires more than labels and conclusions." *Id.* at 545. To survive a motion to dismiss, the complaint must state a plausible claim, not merely conclusory statements deriving from assumptions or inferences. *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1950, 173 L.Ed.2d 868 (2009).

In reviewing a motion to dismiss, it is well-established that a court should "consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim." *M & M Stone Co. v. Pa.*, 388 Fed.Appx. 156, 162 (3d Cir.2010).

III. DISCUSSION

A. STANDING

As an initial matter, this Court must discuss whether jurisdiction is founded in this case, given the requirements of Article III. Defendants say Plaintiffs lack standing because they state no injury in fact. (Def.'s Am. Mot. Dismiss 1, Sept. 30, 2011, ECF No. 51). Under Article III, federal judicial power is restricted to cases and controversies. *Sprint Commc'n Co. v. APCC Servs., Inc.*, 554 U.S. 269, 273, 128 S.Ct. 2531, 171 L.Ed.2d 424 (2008). The case-or-controversy requirement means that Plaintiff must establish standing. *Id.* Without standing, the federal court lacks subject matter jurisdiction and must dismiss the action. *Common Cause of Pa. v. Pa.*, 558 F.3d 249, 257 (3d Cir.2009). Article III standing requires adequate establishment of: 1) an injury in fact, 2) causation, and 3) redressability. *Sprint Commc'n*, 554 U.S. at 273. An injury in fact involves a concrete and particularized and actual or imminent, as opposed to conjectural or hypothetical, invasion of a legally protected interest. *Id.* (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-1, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992)). The causation element of standing requires a connection between the alleged injury in fact and the alleged conduct of the Defendant. *Id.* The redressable element means that it is likely,

and not merely speculative, that the injury in fact would be remedied by the relief sought. *Id.*

*3 Defendants, in their motion to dismiss, explain how Plaintiffs fail to adequately establish the injury in fact element of standing:

In the instant matter, [P]laintiffs summarily allege that they “will incur costs to repair the damages caused by [D]efendants’ unlawful activity” [(Pl.’s Compl. ¶¶ 55 and 64) (emphasis omitted)] without any indication of when or why such costs might be incurred, and while explicitly excluding any allegations of personal injury, either present or future. [(Pl.’s Compl. ¶ 10)] ... Plaintiffs have not alleged present, manifest or even imminent damages, or any adverse consequences whatsoever. The allegations are purely subjective and hypothetical. (Def.’s Am. Mot. Dismiss 7).

Plaintiffs counter that the injury in fact is the cost of buying a product that they would not have bought, had facts that arose later been apparent at the time when they could have made a choice. (Pl.’s Opp’n 10, Mar. 28, 2011, ECF No. 37). In the same vein, Plaintiffs argue that they received something other than what was bargained for. *Id.*

Defendants supply strong argument showing that Plaintiffs fail to adequately establish that the instant scenario demonstrates injury in fact. On the spectrum of proof relevant to injury in fact, Plaintiffs’ case presents more of an “abstract” notion of injury, rather than a harm that is “distinct and palpable.” See *Whitmore v. Arkansas*, 495 U.S. 149, 155, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990) (citing *Warth v. Seldin*, 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343; and *O’Shea v. Littleton*, 414 U.S. 488, 494, 94 S.Ct. 669, 38 L.Ed.2d 674 (1974)). Indeed, it can be assumed from the complaint that Plaintiffs might not have even discovered that “counterfeit mesh” was implanted without the letter from LMC describing the situation as such. Though Plaintiffs cleverly oscillate between contract and tort theories in an attempt to show that a harm amounts to “injury in fact” as envisioned under the standards for Article III standing, their arguments fall short of concrete proof.

Thus, this Court lacks subject matter jurisdiction over Plaintiffs claim and must dismiss. Though no further analysis is required due to the lack of subject matter jurisdiction, this Court will engage in a brief analysis of each Count of the Complaint.

B. Count I: Violation of the New Jersey Consumer Fraud Act (“NJCFA”)

Plaintiffs argue that their NJCFA claims are distinct and sustainable based on an economic injury theory, given they paid a premium for a product based on Defendants’ misrepresentations. See *Id.* at 9; see also *Medley v. Johnson & Johnson Consumer Cos., Inc.*, No. 10-cv-2291, 2011 WL 159674, at *2 n. 2 (D.N.J. Jan.18, 2011) (DMC). Plaintiffs will not establish the elements required by the NJCFA based on the fact that their allegations are “founded in the principals of economic inequities, not tort ...” (Pl.’s Opp’n 5). A claim under the NJCFA requires proof of: 1) an unlawful practice as defined under the Act; 2) ascertainable loss of moneys or property; and 3) a causal relationship between Defendant’s unlawful conduct and Plaintiff’s ascertainable loss. *N.J.S.A. 56:8-19* (1998).

*4 Plaintiffs state that Defendants’ business practice of marketing, advertising and promoting counterfeit *surgical mesh* is “false, misleading, inaccurate and deceptive.” (Pl.’s Compl. ¶ 58). However, Plaintiffs oppose Defendants’ motion to dismiss with argument that focuses almost exclusively upon the heightened pleading requirement Defendants’ suggest, and not at all upon the supplemental evidence that would buttress Plaintiff’s otherwise conclusory claims. The NJCFA requires an unlawful practice such as an affirmative act, a knowing omission or a regulatory violation. *Parker v. Howmedica Osteonics Corp.*, 2008 WL 141628, *2 (D.N.J. Jan.14, 2008) (citation omitted). Plaintiffs did not specifically allege any conduct that tends to amount to an “unlawful practice” under the NJCFA.

Otherwise fatal to Plaintiffs’ claim is the failure of proof problem with the contention that they never received the benefit of the bargain or “paid for a product that was of no value.” (Pl.’s Compl. ¶ 63). Such allegations do not satisfy the NJCFA’s “ascertainable loss” requirement, without more. Though the “counterfeit *surgical mesh*” has a price tag, the “no value” concept of it, considering Plaintiffs do not assert any physical injury or otherwise, is abstract. Plaintiffs do not provide specific proofs of harm to support, or upon which this Court could infer a quantifiable loss. *Thiedemann v. Mercedes-Benz USA, LLC*, 183 N.J. 234, 252, 872 A.2d 783 (2005); see also, *Parker v. Howmedica Osteonics Corp.*, 2008 WL 141628, at *3 (D.N.J. Jan.14, 2008). Stating the expectation of a future loss, similarly fails to meet the requirement of the CFA, because it is too speculative. *Id.* This insurmountable problem is the same as that which precluded

Plaintiff from establishing injury in fact for standing purposes. Plaintiffs fail to state a claim under the NJCFA.

C. Count II: Unjust Enrichment and Common Law Restitution

Plaintiffs may not sidestep Article III standing requirements by basing their claim in contract theory. Plaintiffs allege that they would not have purchased the product if it was not sterile, Bard-manufactured, FDA approved or indicated for surgical use. As such, Plaintiffs contend Defendants were unjustly enriched by their purchase and that they are therefore entitled to restitution. The parties point to a matter previously before this Court, *Koronthaly v. L'Oreal USA, Inc., No. 07-cv-5588*, 2008 WL 2938045 (D.N.J. July 29, 2008), *aff'd*, 374 Fed.Appx. 257 (3d Cir.2010) (Plaintiff asserted lipstick products contained lead in far greater amounts than permitted in candy by the FDA). The Third Circuit reviewed a similar issue of whether a consumer could recover on the basis that she did not know what she was getting or would not have purchased the product had she known certain details about it. *Koronthaly*, 374 Fed.Appx. at 258. In a short opinion, the Court held that the purchases were not made pursuant to a contract and therefore Plaintiff had failed to prove that that which would have precluded her from buying the product had formed part of the basis of any bargain. *Id.* at 259. Plaintiff's claim failed because she did not demonstrate a concrete injury in fact, and it could not otherwise be sustained by artful pleading dependent upon contract theory. *Id.* Despite Plaintiffs' contentions that this case is distinguishable from *Koronthaly*, the fact that Plaintiffs did not actually received the product they intended to purchase and paid for, does not affect Plaintiffs' failing contract claims. Rather, the Third Circuit guides that the focus is upon the harm, or in this case, the lack thereof, rather than the buyer's expectation.

D. Count III: Breach of Express Warranty

*5 Plaintiffs fail to demonstrate specifically that they relied upon labeling or other expressions of promise that could have formed the "basis of the bargain." Plaintiffs frame their breach of express warranty claim almost identically to their breach of implied warranty claims. In other words, Plaintiffs submit no specific proof of promises that were expressed, whether they amounted to, as Plaintiffs suggest, assertions that the product was (1) Bard-manufactured, (2) sterile, (3) FDA

approved, (4) indicated for surgical use or otherwise. Rather, Plaintiffs frame their claims upon assumptions of promise and information that the *surgical mesh* used was counterfeit. Establishing an express warranty requires more substantial proof. Indeed, the Third Circuit held that breach of an express warranty sounds in breach of contract and, as such, Plaintiffs' claim fails for reasons similar to those described in the prior section. *Pritchard v. Liggett & Myers Tobacco Co.*, 350 F.2d 479, 484 (3d Cir.1965). This Court will not assume, even considering LMC's concession that the mesh was counterfeit, that these four expressions were specifically made and relied upon. Such a lack of specificity does not comport with the nature of the theories supporting consumer reliance upon an express warranty.

E. Counts IV and V: Breach of Implied Warranty of Merchantability and Fitness for a Particular Purpose

Defendants convince this Court that, standing alone, the counterfeit nature of the *surgical mesh* "does not demonstrate that [Plaintiffs] or others could not use the product safely." (Pl.'s Opp'n 27). Plaintiffs do not supply any supporting facts, other than the counterfeit designation of the mesh, rendering the product valueless or unfit. Finally, Plaintiffs fail to assert any injury, and in fact disclaim any physical harm, resulting from the product. Plaintiffs again rely on the abstract concept of the mesh's "zero value" without proving specifically how the product failed. Plaintiffs further fail to show that the product is generally or otherwise unfit for the ordinary purpose which it was used. Rather, Plaintiffs declare that the *surgical mesh* continues to work for the purpose for which it was designed, to this day, despite any misrepresentations or omissions regarding the brand or otherwise. Plaintiffs can sustain neither a claim of breach of implied warranty of merchantability nor fitness for a particular purpose.

IV. CONCLUSION

For the foregoing reasons, this Court hereby **grants** Defendants' motion to dismiss Plaintiff's complaint. An appropriate order, filed on this day, follows this opinion.

All Citations

Not Reported in F.Supp.2d, 2012 WL 1964452

TAB 8

 KeyCite Red Flag - Severe Negative Treatment
On Reconsideration [Boyd v. Johnson & Johnson Consumer Companies, Inc.](#),
D.N.J., August 2, 2010

2010 WL 2265317

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Jaimee BOYD and Jessica Pollock, individually and
on behalf of all others similarly situated, Plaintiffs,

v.

JOHNSON & JOHNSON CONSUMER
COMPANIES, INC., Defendant.

Civil Action No. 09-CV-3135 (DMC-MF).

May 31, 2010.

West KeySummary

1 [Sales](#) Nature of Good or Product

Consumer of baby wash and shampoo lacked standing and therefore failed to state a breach of implied warranty claim against the manufacturer. Consumer argued that she suffered economic injury in purchasing the allegedly contaminated product, sufficient to confer standing. However, the products consumer purchased did not contain chemicals explicitly banned by the Food and Drug Administration (FDA) for use in cosmetics. [Fed.Rules Civ.Proc.Rule 12\(b\)\(1\), 28 U.S.C.A.](#)

[1 Cases that cite this headnote](#)

Attorneys and Law Firms

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OPINION

[DENNIS M. CAVANAUGH](#), District Judge.

*1 This matter comes before the Court upon motion by Johnson & Johnson Consumer Companies, Inc. (“Defendant”) to dismiss the Amended Class Action Complaint (“Complaint”) of Jaimee Boyd and Jessica Pollock, individually and on behalf of all others similarly situated, (“Plaintiffs”) for failure to state a claim pursuant to [Fed.R.Civ.P. 12\(b\)\(6\)](#) and for lack of subject matter jurisdiction pursuant to Fed. R. Civ. 12(b)(1). Pursuant to [Fed.R.Civ.P. 78](#), no oral argument was heard. After considering the submissions of all parties, it is the decision of this Court for the reasons herein expressed that Defendant’s motion to dismiss is **granted in part** and **denied in part**.

I BACKGROUND

The Amended Complaint is brought individually and on behalf of all class purchasers (“Class Members”) of J & J’s Baby Shampoo and/or Aveeno Baby Wash and Shampoo (“products”). (Plaintiffs’ Complaint (“Pl.Compl.”), ¶ 1). Plaintiffs allege that “although Defendant represented that the products it made, marketed, distributed, promoted and sold were safe for children, its Children’s Personal Care Products were actually contaminated with toxic chemicals linked to increased [cancer](#) risk, adverse skin reactions, and other serious health problems.” (Pl.Compl., ¶ 2). Plaintiffs further allege that despite representations made by Defendant that their products are safe and gentle, these products contain contaminants that are not disclosed on the label and that could otherwise have been removed, or at least reduced, pursuant to a process called vacuum stripping. (Pl.Compl., ¶¶ 2, 5).

Plaintiffs assert that independent lab tests, conducted in accordance with regulations promulgated by the Environmental Protection Agency (“EPA”), reveal that J & J’s Baby Shampoo contains methylene chloride in levels as high as 1.1 ppm, 1,4 dioxane levels as high as 38 ppm, and formaldehyde levels as high as 210 ppm. (Pl.Compl., ¶¶ 3, 44). “After testing, [J & J’s] Aveeno Baby Wash and Shampoo was found to be contaminated with 1,4-dioxane. Independent Lab Tests found 1,4-dioxane levels of 13 ppm.” (Pl.Compl., ¶ 54). Plaintiffs also assert that each of the foregoing qualifies as a cosmetic pursuant to the Food Drug and Cosmetic Act because each is “intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance” and is not “soap.” [21 U.S.C. § 321\(i\) \(2008\)](#). (Pl.Compl., ¶¶ 48, 58).

Count I of the Complaint asserts a claim for breach of implied warranty pursuant to the [Uniform Commercial Code \(“UCC”](#)) § 2-314. (Pl.Compl.¶ 83). Count II of the Complaint asserts a claim for breach of implied warranties of merchantability and fitness for a particular use. (Pl.Compl., ¶ 90). Count III of the Complaint asserts a claim for unfair and deceptive trade practices. (Pl. Compl ., ¶ 95). Count IV of the Complaint asserts a claim for unjust enrichment. (Pl.Compl., ¶ 103).

II. STANDARD OF REVIEW

*2 “There is a fundamental difference of review under [Rule 12\(b\) \(1\)](#), where the existence of disputed facts will not preclude the court from evaluating the merits of the jurisdictional claim, and [Rule 12\(b\)\(6\)](#) where the court is required to accept as true all the allegations of the complaint and all inferences arising from them.” *Anjelino v. New York*, 200 F.3d 73, 87 (3d Cir.1999). “[T]he threshold to withstand a motion to dismiss under [Rule] 12(b)(1) is thus lower than that required to withstand a [Rule 12\(b\)\(6\)](#) motion.” *Kehr Packages Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir.1991)).

A. Fed.R.Civ.P. 12(b)(6)

“The [d]istrict [c]ourt, in deciding a motion under [Fed.R.Civ.P. 12\(b\)\(6\)](#), [is] required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [Plaintiff].” *Phillips v. County of Allegheny*, 515 F.3d 224, 228 (3d Cir.2008). “While a complaint attacked by a [Rule 12\(b\)\(6\)](#) motion to dismiss does not need detailed factual allegations, [] a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). “[A court is] not bound to accept as true a legal conclusion couched as a factual allegation.” *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986). “Factual allegations must be enough to raise a right to relief above a speculative level, [] on the assumption that all factual allegations in the complaint are true (even if doubtful in fact).” *Bell*, 550 U.S. at 555–56.

B. Fed.R.Civ.P. 12(b)(1)

“On a [Rule 12\(b\)\(1\)](#) motion, no presumption of truthfulness attaches to the allegations of the plaintiff.” *CNA v. United*

States, 535 F.3d 132, 139 (3d Cir.2008). A facial attack “concerns ‘an alleged pleading deficiency’ whereas a factual attack concerns the actual failure of [a plaintiff’s] claims to comport [factually] with the jurisdictional prerequisites.” *Id.* (citing *U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir.2007)).

III. DISCUSSION

A. Standing

To bring a suit in a federal court, Plaintiffs must have standing pursuant to Article III of the United States Constitution. To establish standing under Article III, Plaintiffs must show: (1) injury in fact; (2) causation; and (3) redressability. *Horvath v. Keystone Health Plan E., Inc.*, 333 F.3d 450, 455 (3d Cir.2003); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992).

First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

*3 *Id.* (citing *AT & T Communications of N.J., Inc. v. Verizon N.J., Inc.*, 270 F.3d 162, 170 (3d Cir.2001)). “The injury must affect the plaintiff in a personal and individual way.” *Pitt News v. Fisher*, 215 F.3d 354 (3d Cir.2000); *Alston v. Countrywide Fin. Corp.*, 585 F.3d 753, 763 (3d Cir.2009).

“[O]rdinarily, one may not claim standing to vindicate the constitutional rights of some third party.” *Pitt*, 215 at 362. “We apply this prudential rule against third party standing even when the requirements of Article III have been met, to ‘avoid deciding questions of broad social import ... [and]

to limit access to the federal courts to those litigants best suited to assert a particular claim.’ “ *Id.* (citing *Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 99–100, 99 S.Ct. 1601, 60 L.Ed.2d 66 (1979)). “[W]hen the asserted harm is a ‘generalized grievance’ shared in substantially equal measure by all or a large class of citizens, that harm alone normally does not warrant exercise of jurisdiction.” *Berg v. Obama*, 586 F.3d 234, 239 (2009) (citing *Warth v. Seldin*, 422 U.S. 490, 499, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975)). Furthermore, “[t]he standing inquiry does not change in the context of a putative class action.... [S]tanding cannot be predicated on an injury which the plaintiff has not suffered, nor can it be acquired through the back door of a class action.” *Koronthaly v. L’Oreal*, 2008 U.S. Dist. LEXIS 59024, * 12 (D.N.J. July 25, 2008).

Defendant contends that “Plaintiff[s]’ failure to plead any manifest, present, non-speculative injury, and failure to allege that [the products] did not provide cleansing benefits” requires the Court to conclude that Plaintiffs lack standing in the instant matter. In reliance upon this Court’s decision in *Koronthaly*, Defendant asserts that Plaintiffs’ demand for a refund of the purchase price as a consequence of exposure to Defendant’s products fails to establish an injury-in-fact and therefore, is not sufficient to confer standing where the alleged harm is no more than conjectural or hypothetical. As a result, Defendant claims that the absence of a cognizable injury and thereby standing in this matter requires dismissal pursuant to Fed.R.Civ.P. 12(b)(1).

In response, Plaintiffs contend that economic injury is sufficient to confer standing in this matter, relying upon *Clinton v. City of New York*, 524 U.S. 417, 118 S.Ct. 2091, 141 L.Ed.2d 393 (1998) and *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286 (3d Cir.2005). Plaintiffs contend that where the product contains undisclosed toxins and an ingredient banned by the FDA, the injury arises at the time of purchase. In distinguishing the *Koronthaly v. L’Oreal* case, citing to this Court’s disposition on a motion for reconsideration, Plaintiffs assert that unlike *Koronthaly* where this Court determined that plaintiff “provided no authoritative evidence that the lead levels in defendants’ lipstick products constitute[d] a dangerous amount or [were] in some way prohibited[,]” the present action involves methylene chloride, a substance banned by the FDA for use in cosmetics. 2008 U.S. Dist. LEXIS 86419, *11 (D.N.J. Oct. 24, 2008). Further, Plaintiffs contend that the EPA classifies the other chemicals at issue as probable carcinogens. Lastly, Plaintiffs assert that their claims should stand because Plaintiffs have at least raised an issue

of fact with respect to whether the chemicals contained in Defendant’s products are dangerous in amount.

*4 The *Koronthaly* case involved the purchase of a lipstick containing lead, the content of which was not subject to FDA regulation. *Id.* at *2–3. However, the lead content of the lipstick appeared dangerous when compared to the lead content regulation imposed by the FDA on candy. *Id.* In the absence of an FDA regulation concerning lead content in lipstick, or other legal prohibition, the plaintiff could not “seek a remedy for a harm that she ha[d] not actually or allegedly suffered.” Moreover, this Court accorded great weight to the decision in *Williams v. Purdue Pharma Co.*, 297 F.Supp.2d 171 (D.D.C.2003), concluding that the “plaintiffs’ allegation of an economic injury in a products liability action was insufficient to establish injury-in-fact” because “without alleging that a product failed to perform as advertised, a plaintiff has received the benefit of his bargain and has no basis to recover purchase costs.” *Id.* at *13–14. Therefore, the *Williams* Court “remarked that benefit of the bargain injury could not sustain a claim of injury in fact.” *Id.*

While the Court agrees that the assertion of an economic injury is not an automatic bar to standing, *Koronthaly* demonstrates that an exception has been recognized in the context of claims concerning defective products, absent a specific legal prohibition precluding particular ingredients or usages. Insofar as Plaintiffs’ claims pertain to allegedly toxic chemicals that have not been banned by the FDA for use in cosmetics, including 1,4-dioxane and formaldehyde, in accordance with *Koronthaly*, this Court concludes that any potential injury is too remote, hypothetical and/or conjectural to establish standing in this matter. However, insofar as Plaintiffs’ claims pertain to methylene chloride, a chemical explicitly banned for use by the FDA in any cosmetic, this Court declines to dismiss Plaintiffs’ claims pursuant to Fed.R.Civ.P. 12(b)(1) for lack of standing. As alleged, Plaintiff Boyd only purchased J & J’s Baby Shampoo, which contains methylene chloride, (Pl.Compl., ¶¶ 8, 44) and Plaintiff Pollack only purchased Aveeno Baby Wash and Shampoo, which does not contain methylene chloride. (Pl.Compl., ¶¶ 9, 54) At this stage, only Plaintiff Boyd is permitted to proceed with respect to her claims concerning J & J’s Baby Shampoo. Any claims pertaining to Plaintiff Pollack’s use of Aveeno Baby Wash and Shampoo are dismissed in their entirety.

B. Choice of Law

As a federal district court sitting in diversity, this Court must apply the choice of law rules of New Jersey, the forum state. *See Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496-97, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941). New Jersey's choice of law rules mandate that the determinative law is that of the state with the greatest interest in governing the particular issue. The first step is to determine whether a conflict exists between the law of interested states, and then any conflict shall be determined on an issue-by-issue basis. "Under general conflict of laws principles, where the laws of the two jurisdictions would produce the same result on the particular issue presented, there is a 'false conflict,' and the court should avoid the choice-of-law question." *Williams v. Stone*, 109 F.3d 890, 894 (3d Cir.1997). If there is a conflict, then the court must identify the governmental policies underlying the law of each state and how those policies are affected by each state's contacts to the litigation. If the state's law is not related to its contacts with the litigation, then the state does not have an interest in having its law applied to the underlying issue. *See Vezey v. Doremus*, 103 N.J. 244, 510 A.2d 1187, 1189 (N.J.1986). That is, if there is an actual conflict between the two states' laws, the court then determines "which state has the most meaningful connections with and interests in the transaction and the parties." *Spence-Parker v. Del. Riv. & Bay Authority*, 2009 U.S. Dist. LEXIS 75187, *20 (D.N.J. Aug. 21, 2009). Where no actual conflict of law exists, no choice of law need be made. *See Zavala v. Wal-Mart Stores, Inc.*, 393 F.Supp.2d 295, 333 (D.N.J.2005). "If there is no actual conflict, the court must apply the law of New Jersey." *LNT Merck Co. v. Dyson, Inc.*, 2009 U.S. Dist. LEXIS 62308, *6 (D.N.J. July 21, 2009) (citing *Lebegern v. Forman*, 471 F.3d 424, 428 (3d Cir.2006)). In that instance, a motion to dismiss under Fed.R.Civ.P. 12(b)(6) should be decided under New Jersey law. *See Gallerstein v. Berkshire Life Ins. Co. of America*, 2006 U.S. Dist. LEXIS 64487, *3 (D.N.J. Sept. 11, 2006).

*5 The parties' moving papers recognize that the outcome is the same regardless of whether New Jersey State Law, Colorado State Law, or Pennsylvania State Law is applied to this diversity action. Therefore, the parties assert that no conflict of laws issue is present in the instant matter.

1. New Jersey State Law Breach of Warranty, Consumer Fraud and Unjust Enrichment Claims

Defendant asserts that dismissal is required with respect to all Plaintiffs' claims because the claims are based on alleged harm caused by a product and as a consequence, are subsumed by the New Jersey Product Liability Act

("PLA"). Plaintiffs argue that the PLA does not subsume Plaintiffs' UCC or consumer protection claims because Plaintiffs neither assert themselves as "claimants" nor allege present or future physical injuries as a consequence of Defendant's products. Plaintiffs further allege that the heart of the present matter is the economic harm caused by Defendant's misrepresentations, omissions and breaches of warranty. Additionally, Plaintiffs contend that the instant matter does not present a risk of double recovery, and that the claims asserted do not constitute a failure to warn cause of action pursuant to the PLA.

The New Jersey Supreme Court decision in *Sinclair v. Merck & Co.* is instructive. In *Sinclair v. Merck & Co.*, the Plaintiffs "alleged that as a result of their direct and prolonged consumption of Vioxx, they are at enhanced risk of serious undiagnosed and unrecognized myocardial infarction, commonly referred to as 'silent heart attack,' and other latent and unrecognized injuries." 195 N.J. 51, 55, 948 A.2d 587 (2008). In that case, the plaintiffs asserted claims for negligence, violation of the Product Liability Act, violation of the Consumer Fraud Act, breach of express and implied warranties and unjust enrichment. *Id.* In dismissing the complaint in its entirety, New Jersey Supreme Court determined the following,

[p]laintiffs seek to avoid the requirements of the PLA by asserting their claims as CFA claims. However, the Legislature expressly provided in the PLA that claims for "harm caused by a product" are governed by the PLA "irrespective of the theory underlying the claim." N.J.S.A. 2A:58C-1b(3). We explained in *Lead Paint*, *supra*, that "[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action in relating to harms caused by consumer and other products." 191 N.J. at 436-37, 924 A.2d 484. As a result, we declared that "[i]n light of the clear intention of our Legislature to include all [product liability] claims within the scope of the PLA, we find no ground on which to conclude that the claims being raised by plaintiffs, regarding an ordinary household product used by consumers, were excluded from the scope of" the PLA. We reach the same conclusion here.

The language of the PLA represents a clear legislative intent that, despite the broad reach we give to the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product. The heart of plaintiffs' case is the potential for harm caused by Merck's drug. It is obviously a product liability claim. Plaintiffs' CFA claim does not

fall within an exception to the PLA, but rather clearly falls within its scope. Consequently, plaintiffs may not maintain a CFA claim.

*6 *Id.*^{1 2}

¹ Although this Court permitted the CFA claims to proceed in *Nafar v. Hollywood Tanning Sys., Inc.*, in that case, the Plaintiff's claims and basis for distinction of the CFA from the PLA was the purchase of services, rather than the purchase of a defective product. 2007 U.S. Dist. LEXIS 26312, *12–14 (D.N.J. Apr. 5, 2007). CFA claims rooted in services are clearly distinguishable from claims grounded in products. The present action does not involve a claim for defective services.

² Further, *In re Ford Motor Co. E-350 Van Products*, 2008 U.S. Dist. LEXIS 73690, *48 n. 9 (D.N.J. Sept. 3, 2008), where the Court found the Sinclair case “inapposite” “because, by design, the PLA ‘except[s] actions for harm caused by breach of an express warranty[,]’ which plaintiffs expressly allege [d.]” On the basis of an express warranty, the Court concluded that *Sinclair* decision “does not mandate dismissal of unjust enrichment and state consumer fraud claims where a party does not plead a PLA claim.” *Id.* (internal citations omitted). Plaintiffs do not assert a claim for breach of an express warranty in the present action.

Similarly, at the heart of this matter is the potential for harm caused by the defective products, J & J Baby Shampoo and/or Aveeno Baby Shampoo and Wash, containing allegedly “toxic chemicals linked to increased [cancer](#) risk, adverse skin reactions, and other serious health problems.” (Compl., ¶ 2). Further, Plaintiffs allege that the products were rendered useless “because they were contaminated with dangerous and potentially cancer-causing chemicals and continued use of the products would require Plaintiffs and Class Members to knowingly continue and even increase the exposure of their vulnerable infants and children to the harmful contaminants.” (Compl., ¶ 2).

Consistent with the *Sinclair* decision, this Court concludes that the PLA subsumes all of Plaintiffs' claims, effectively precluding Plaintiffs' claims with respect to the CFA, and otherwise, in the absence of “harm” as defined by the PLA. The Court does not agree that articulating a claim in terms of pure economic harm where the core issue is the potential

injury arising as a consequence of the products' allegedly harmful chemicals converts the underlying defective product claim into an independent and unrelated consumer fraud issue. Indeed, Plaintiffs' original Complaint contains a cause of action for products liability strategically omitted from the amended Complaint. Limiting a claim to economic injury and the remedy sought to economic loss cannot be used to obviate the PLA.

The assertion of a claim pursuant to the PLA is premised upon a requisite level of harm, including:

(a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.

N.J.S.A. 2A:58C-1b(2). Harm, for purposes of the PLA, does not include pure economic loss. Insofar as Plaintiffs concede that their injury is purely economic, Plaintiffs' claims cannot survive. Therefore, with respect to New Jersey law, in accordance with *Sinclair*, Plaintiffs' Complaint is dismissed in its entirety.

2. Colorado State Law Breach of Warranty, Consumer Fraud and Unjust Enrichment

Despite the parties' respective beliefs that there is no conflict of law issue present in the instant matter, it is not clear to the Court that product liability laws of Colorado subsume related claims in the same manner as the New Jersey PLA³. Therefore, upon dismissal of all New Jersey State Law claims and for purposes of inclusion, the Court will proceed by addressing the viability of Plaintiffs' claims under Colorado State Law. If Plaintiff Boyd has asserted viable claims pursuant to Colorado State Law, then a conflict of law exists and the Court will undertake to ascertain which state has the superior interest in the litigation.

³ The Court will not address the viability of Plaintiffs' claims pursuant to Pennsylvania law since Plaintiff

Pollack's portion of the Complaint was dismissed for lack of standing.

i. Consumer Fraud

*7 Defendant contends that Plaintiffs have no viable claims pursuant to Colorado State Laws because Plaintiffs fail to allege any non-speculative, ascertainable loss and fail to plead their claims with particularity in accordance with Fed.R.Civ.P. 9(b). Plaintiff Boyd claims that "ascertainable loss is not a distinct element under [the Colorado Consumer Protection Act ("CCPA")], and [pursuant to Colorado State Law], the Court may look to its analysis of other states' laws." (Pl. Br. at 33). Plaintiff also alleges that she suffered "ascertainable loss to the extent [she] paid for a product and got something less than what was promised." (Pl. Br. at 28).

"[A] CCPA claim arises when a party knowingly makes a misrepresentation or makes a false representation that has the capacity to deceive." *Rhino Listings USA, Inc. v. Rocky Mountain Rhino Listings, Inc.*, 62 P.2d 142, 148 (Colo.2003). The CCPA "deters and punishes businesses which commit deceptive practices in their dealings with the public by providing prompt, economical, and readily available remedies against consumer fraud." *Id.* at 146. To prove a private cause of action under COLO. STAT. ANN. § 6-1-113, a plaintiff must show: (1) that the defendant engaged in an unfair or deceptive trade practice; (2) that the challenged practice occurred in the course of defendant's business, vocation, or occupation; (3) that it significantly impacts the public as actual or potential consumers of the defendant's goods, services, or property; (4) that the plaintiff suffered injury in fact to a legally protected interest; and (5) that the challenged practice caused the plaintiff's injury." *Hall v. Walter*, 969 P.2d 224, 234 (Colo.1998). "The CCPA is silent as to specific injuries for which it intends to provide a remedy." *Id.* at 236. See also *Crowne v. Tull*, 126 P.3d 196, 209 (Colo.2006). "[The CCPA's] focus lies with defining prohibited actions that are likely to injure the public and specifying civil penalties and private remedies available for these violations." *Hall*, 969 P.2d at 224. "[I]n determining whether conduct falls within the purview of the CCPA, it should ordinarily be assumed that the CCPA applies to the conduct ... because of the strong and sweeping remedial purposes of the CCPA." *Showpiece Homes Corp. v. Assurance Co. of Am.*, 38 P.3d 47, 51 (Colo.2001). Given the CCPA's policy of providing a private action where a defendant's conduct has a significant impact on the public, Plaintiff Boyd's claims pertaining to J & J Baby Shampoo may proceed under Colorado State Law.

Although foreclosed by application of the PLA in the instant case, the CFA was enacted to "protect the consumer against imposition and loss as a result of fraud and fraudulent practices by persons engaged in the sale of goods and services." *Smith v. Alza*, 400 N.J.Super. 529, 552, 948 A.2d 686 (2008). "The CCPA was enacted to regulate commercial activities and practices which, because of their nature, may prove injurious, offensive, or dangerous to the public." *Rhino Listings*, 62 P.2d at 146 (citing *People ex rel. Dunbar v. Gym of America, Inc.*, 177 Colo. 97, 493 P.2d 660, 667 (Colo.1972)). Beyond the underlying governmental purpose of the CCPA, Plaintiff Boyd in this action resides in Colorado and presumably, the purchase of the allegedly defective product occurred in Colorado. J & J is a New Jersey corporation engaged in business throughout the United States, including Colorado. Therefore, Colorado State contacts in the instant matter seem to outweigh New Jersey State contacts. Colorado State Law prevails with respect to this issue.

ii. Breach of Implied Warranty

*8 Defendant asserts that Plaintiffs' breach of implied warranty claims should be dismissed because Plaintiffs' Complaint fails to allege that the products were not merchantable or failed to perform the function for which they were sold, and because the complaint fails to allege any purpose that is separate and apart from the ordinary purpose. (Def. Br. at 33-34). Plaintiffs' Complaint asserts a claim for breach of implied warranties because the goods were allegedly not fit for their ordinary purpose or particular use on children and further, because the products fail to conform to the promises and representations made on the labels. Specifically, Plaintiffs allege that the products are not merchantable because they are contaminated with methylene chloride. (Pl. Br. at 35-36).

"Colorado case law recognizes that [warranties of merchantability and fitness for a particular purpose] may coexist when there is sufficient evidence to support the creation of each warranty." *Palmer v. A.H. Robins Co., Inc.*, 684 P.2d 187, 209 (Colo.1984). "Under Colorado [State] [L]aw, a warranty of fitness for a particular purpose does not arise when a product is purchased for the ordinary purpose for which the device or product is to be used." *Hauck v. Michelin North Am., Inc.*, 343 F.Supp.2d 976 (D.Colo.2004) (citing *Weir v. Federal Insurance Co.*, 811 F.2d 1387, 1393 (10th Cir.1987)). "To establish a prima facie case for breach of implied warranty for fitness for a particular purpose, the plaintiff must show that: (1) the

defendant sold and impliedly warranted the product to be fit for a particular purpose; (2) the plaintiff was reasonably expected to use the product; (3) the product was not suitable for the purpose warranted; and (4) the breach was a cause of the plaintiff's injuries." *Simon v. Coppola*, 876 P.2d 10 (Colo.Ct.App.1993). "[W]arranties of merchantability, if all other statutory prerequisites have been met, arise in every contract for sale, unless properly excluded." *Graham Hydraulic Power, Inc. v. Stewart & Stevenson Power, Inc.*, 797 P.2d 835, 838 (Colo.Ct.App.1990).

In order for goods to be merchantable, they must be at least as such as:

- (a) pass without objection in trade under the contract description; and
- (b) in the case of fungible goods, are of fair average quality within the description; and
- (c) are fit for the ordinary purposes for which such goods are used; and
- (d) run, within the variations permitted by the agreement, of even kind, quality, and quantity within each unit and among all units involved; and
- (e) are adequately contained, packaged, and labeled as the agreement may require; and
- (f) conform to the promises or affirmations of fact made on the container or label if any.

COLO. STAT. ANN. § 4-2-314. Assuming, without concluding, that the descriptive messages on the alleged defective products constitute promises or affirmations, then, in accordance with the foregoing limitations, Plaintiff's claims for breach of implied warranties pursuant to Colorado State Law are permitted to proceed.

*9 Although foreclosed by application of the PLA in the instant matter, the underlying purpose of the UCC as recognized by the New Jersey Supreme Court, is "to simplify, clarify and modernize the law governing commercial transactions; to permit the continued expansion of commercial practices through custom, usage and agreement of the parties; and to make uniform the law among various jurisdictions." N.J. S.A. 12A:1-102(1); *Alloway v. General Marine Indus., L.P.*, 149 N.J. 620, 630, 695 A.2d 264 (1997). Codified under title 4 of Colorado State Law, Colorado State Law adheres to the same underlying purposes

as New Jersey. See *Proactive Tech., Inc. v. Denver Place Assoc. Ltd. P'ship*, 141 P.3d 959, 961 (Colo.Ct.App.2006). Similar to the foregoing analysis, Colorado's contacts with the representative Plaintiff and the transactions that are the source of Plaintiff Boyd's claims favor the application of Colorado law over New Jersey with respect to this issue.

iii. Unjust Enrichment

Defendant asserts that unjust enrichment is not a proper remedy available in this case because Plaintiffs fail to assert that the products failed to perform. By contrast, Plaintiffs assert that they purchased the products conferring a monetary benefit upon the Defendant for useless products that they would not otherwise have purchase, but for the representations that the products were safe, gentle and/or mild. To sustain a claim for unjust enrichment under Colorado law, a plaintiff "must prove that: (1) the defendant received a benefit (2) at the plaintiff's expense (3) under circumstances that would make it unjust for the defendant to retain the benefit without commensurate compensation." *Lewis v. Lewis*, 189 P.3d 1134, 1141 (Colo.2008). "Actions seeking monetary damages are considered legal while actions seeking to invoke the coercive power of the court, such as those seeking injunctions or specific performance, are deemed equitable." *American Family Mut. Ins. Co. v. DeWitt*, 218 P.3d 318, 324 (Colo.2009) (citing *Paterson v. McMahon*, 99 P.3d 594, 597-98 (Colo.2004)); see also *Salzman v. Bachrach*, 996 P.2d 1263, 1265 (explaining restitution is an equitable remedy). Generally, equitable remedies are not available, however, when there is a "plain, speedy, [and] adequate remedy at law." *Szaloczi v. John R. Behrmann Revocable Trust*, 90 P.3d 835, 842 (Colo.2004). "When plaintiffs have an adequate remedy at law for damages, [equitable remedies] will not lie." *Mahoney Marketing Corp. v. Sentry Builders of Colorado, Inc.*, 697 P.2d 1139, 1140 (Colo.Ct.App.1985). Plaintiff explicitly and exclusively alleges economic injury. Therefore, there is no indication that a remedy at law would be inadequate. To the extent that Plaintiff Boyd asserts a claim for unjust enrichment pursuant to Colorado State Law, Plaintiff's Complaint is dismissed.

IV. CONCLUSION

For the foregoing reasons, Defendant's motion is **granted in part** and **denied in part**. Plaintiff's Complaint is **partially dismissed without prejudice** pursuant to Fed.R.Civ.P. 12(b)(1) and Fed.R.Civ.P. 12(b)(6). An appropriate Order accompanies this Opinion.

All Citations

Not Reported in F.Supp.2d, 2010 WL 2265317

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TAB 9

548 Fed.Appx. 761

This case was not selected for publication in the Federal Reporter.

Not for Publication in West's Federal Reporter.

See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also Third Circuit LAR, App. I, IOP 5.7. (Find CTA3 App. I, IOP 5.7)

United States Court of Appeals,
Third Circuit.

James S. CALENDER; Diane
Calender, H/W, Appellants

v.

NVR INC, trading as Ryan Homes; John
Does # 1–10, (fictitious names); ABC
Companies # 1–10 (fictitious names).

No. 12-4132.

Submitted under Third Circuit
LAR 34.1(a) on Nov. 7, 2013.

Opinion filed: Dec. 13, 2013.

Synopsis

Background: Homeowner brought state-court action against company that designed, manufactured, built, and sold his home, asserting claims for negligence, products liability, breach of contract, and breach of warranties. After action was removed, the United States District Court for the District of New Jersey, [Noel L. Hillman, J., 2011 WL 4593759](#), dismissed homeowner's design defect claim, and thereafter, [2012 WL 4482009](#), granted summary judgment for company on remaining claims. Homeowner appealed.

Holdings: The Court of Appeals, [Roth](#), Circuit Judge, held that:

[1] New Jersey affidavit of merit statute applied to homeowner's design defect claim;

[2] homeowner's common-law claims of negligence and implied breach of warranty were subsumed by New Jersey Products Liability Act (PLA); and

[3] company had no duty to warn of danger of falling through home's attic access panel, precluding its liability under PLA.

Affirmed.

Procedural Posture(s): On Appeal; Motion to Dismiss; Motion for Summary Judgment.

West Headnotes (3)

[1] **Negligence** ↗ Affidavit or certification of expert

Products Liability ↗ Buildings and building components and materials

Products Liability ↗ Affidavit or certification of expert

New Jersey affidavit of merit statute applied to homeowner's design defect claim against company that designed, manufactured, built, and sold his home, which sought damages for personal injuries resulting from alleged negligence of company's architect in designing home's attic access panel/opening, through which homeowner fell and was injured, and therefore homeowner's failure to timely provide required affidavit of merit required dismissal of claim; pleading or demonstrating claim would require expert testimony from architect, engineer, or comparable licensed person. [N.J.S.A. 2A:53A-26, 2A:53A-27, 2A:53A-29](#).

1 Cases that cite this headnote

[2] **Contracts** ↗ Nature and Form of Remedy

Products Liability ↗ Buildings and building components and materials

Products Liability ↗ Nature and form of remedy

Homeowner's common-law claims of negligence and implied breach of warranty against company that designed, manufactured, built, and sold his home were subsumed by New Jersey Products Liability Act (PLA), which governed all claims for harm caused by product under New Jersey law, except for claims alleging breach of express warranty. [N.J.S.A. 2A:58C1\(b\)\(3\)](#).

2 Cases that cite this headnote

[3] **Products Liability** Obvious danger
Products Liability Buildings and building components and materials

Danger that one could fall while attempting to enter or exit home's attic through open access panel in ceiling was open and obvious to an ordinary person, and therefore company that designed, manufactured, built, and sold home to homeowner had no duty to warn, precluding its liability under New Jersey Products Liability Act (PLA) for injuries that homeowner sustained when he fell while exiting attic through access panel. [N.J.S.A. 2A:58C-2, 2A:58C-3\(a\)\(2\)](#).

3 Cases that cite this headnote

***762** On Appeal from the United States District Court for the District of New Jersey, (D.C. No. 1-10-cv-04277) District Judge: Honorable [Noel L. Hillman](#).

Attorneys and Law Firms

[Gary F. Piserchia](#), Esq., Mount Laurel, NJ, for Appellants.

[David A. Haworth](#), Esq., Ballard Spahr, Cherry Hill, NJ, [Joseph Kernen](#), Esq., [Brian M. Robinson](#), Esq., Dla Piper, Philadelphia, PA, for NVR Inc, trading as Ryan Homes.

Before: [GREENAWAY, Jr.](#), [VANASKIE](#) and [ROTH](#), Circuit Judges.

OPINION

[ROTH](#), Circuit Judge:

James S. Calender and Diane Calender appeal the District Court's September 30, 2011, order granting defendant NVR, Inc.'s, Motion to Dismiss and the court's September 26, 2012, order granting summary judgment in favor of NVR. For the following reasons, we will affirm the District Court's orders.

I. Background

Calender¹ purchased a newly constructed home from NVR on March 28, 2008. NVR designed, manufactured, built, and sold the home. On October 21, 2008, Calender went up into the home's attic to change the air filter on an air conditioning unit. While exiting the attic through the access panel/opening, Calender fell and was injured.

¹ Although both James and Diane Calender were named plaintiffs in this suit, we refer to only James Calender, except where noted, for convenience and because the facts of the case pertain to him.

Calender filed suit on June 30, 2010, in the Superior Court of New Jersey, Law *763 Division, Camden County, alleging that NVR (1) negligently designed, manufactured, constructed, and/or sold the home; (2) is subject to product liability because the attic access panel/opening was unreasonably dangerous and defective; (3) breached its contract to provide a safe, suitable home; and (4) breached its express and implied warranties. The complaint also included a claim for loss of consortium.

NVR removed the suit to the U.S. District Court for the District of New Jersey.² The District Court dismissed the design defect claim for failure to comply with the New Jersey Affidavit of Merit Statute, [N.J. Stat. Ann. § 2A:53A-26 et seq.](#) A year later, the District Court granted summary judgment in favor of NVR on the remaining claims.

² The District Court had jurisdiction under [28 U.S.C. § 1332](#) because the Calenders are citizens of New Jersey and NVR is incorporated and has its principal place of business in Virginia and the amount in controversy exceeds the jurisdictional amount. We have jurisdiction pursuant to [28 U.S.C. § 1291](#).

II. Analysis

A. Motion to Dismiss the Design Defect Claim

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” [Ashcroft v. Iqbal](#), 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting [Bell Atl. Corp. v. Twombly](#), 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). We exercise plenary review over the District Court's granting of a motion to dismiss. [Institutional Invs. Grp. v. Avaya, Inc.](#), 564 F.3d 242, 251 (3d Cir.2009).

The Affidavit of Merit Statute requires a plaintiff in a personal injury action, alleging negligence or malpractice by a licensed person, to provide an affidavit from a different licensed person that states that there is a reasonable likelihood that the alleged conduct fell outside acceptable professional or occupational standards. *N.J. Stat. Ann. § 2A:53A-27*. Failure to provide the affidavit is deemed a failure to state a cause of action, *id. § 2A:53A-29*, and a dismissal under the statute is with prejudice. *Cornblatt v. Barow*, 153 N.J. 218, 708 A.2d 401, 413 (1998). Architects are included in the statute's list of "licensed persons." *Id. § 2A:53A-26*.

[1] In determining whether an affidavit of merit is required, courts must consider (1) whether the action is for damages for personal injuries, (2) whether the action is for malpractice or negligence, and (3) whether the care, skill, or knowledge exercised or exhibited that is the subject of the complaint fell outside acceptable professional or occupational standards. *Couri v. Gardner*, 173 N.J. 328, 801 A.2d 1134, 1137 (2002) (internal citations and quotation marks omitted). Here, the first two elements are met because Calender's action is for damages for personal injuries as a result of malpractice or negligence. The third element is also met because the action alleges negligence on the part of NVR's architect in designing the attic access panel/opening. As the District Court found, the claim is essentially one for professional malpractice or negligence in the field of architecture. Pleading or demonstrating this claim would require expert testimony from an architect, engineer, or comparable licensed person. Whether Calender's claim is characterized as one for professional negligence or malpractice, or one for strict product liability, we agree with the District Court that Calender is necessarily challenging architectural designs and plans—plans that only a licensed architect would be able to produce.

*764 We conclude that Calender's design defect claim meets all three Couri factors and, accordingly, the Affidavit of Merit statute applies. We will therefore affirm the District Court's dismissal of the design defect claim for plaintiff's failure to timely provide the required affidavit of merit.

B. Summary Judgment on Other Claims

A court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Fed.R.Civ.P. 56(a)*. We exercise plenary review over a district court's grant of summary judgment, and view the facts in the light most favorable to the non-moving party. *Nat'l*

Amusements Inc. v. Borough of Palmyra, 716 F.3d 57, 62 (3d Cir.2013).

Except for claims for breach of an express warranty, all claims for harm caused by a product under New Jersey law, regardless of the theory underlying the claim, are governed by the New Jersey Products Liability Act (PLA). *N.J. Stat. Ann. § 2A:58C1(b)(3)*. The PLA encompasses "virtually all possible causes of action relating to harm caused by consumer and other products." *In re Lead Paint Litig.*, 191 N.J. 405, 924 A.2d 484, 503 (2007). The PLA does not recognize negligence or implied breach of warranty as separate claims for harm caused by a product. *See Port Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 313 (3d Cir.1999). Rather, the PLA is the exclusive remedy for such actions and other claims are subsumed within the statutory cause of action. *See id.*

[2] Calender properly brought this action under the PLA. The District Court was correct that Calender may not proceed with his common-law claims of negligence and implied breach of warranty because those claims are subsumed by the PLA. We will therefore affirm the grant of summary judgment for NVR on those claims.

The PLA provides that a seller or manufacturer may be liable if a product does not contain adequate warnings or instructions. *N.J. Stat. Ann. § 2A:58C-2*. However, no duty to warn exists where the danger presented by a product is "open and obvious." *McWilliams v. Yamaha Motor Corp., U.S.A.*, 987 F.2d 200, 202–03 (3d Cir.1993); *Mathews v. Univ. Loft Co.*, 387 N.J.Super. 349, 903 A.2d 1120, 1124–25 (Ct.App.Div.2006); *see also N.J. Stat. Ann. § 2A:58C-3(a)(2)* (stating that seller or manufacturer is not liable if the unsafe aspect of the product is an "inherent characteristic of the product ... that would be recognized by the ordinary person").

[3] We agree with the District Court's conclusion that the danger that one might fall while attempting to enter or exit the attic through the open access panel in the ceiling is open and obvious to an ordinary person. *Cf. Mathews*, 903 A.2d at 1124 (danger of falling from six-foot-high loft bed was open and obvious). We will affirm the District Court's grant of summary judgment in favor of NVR on this claim because there was no duty to warn.

Finally, the District Court was correct that Diane Calender's loss of consortium claim was derivative of James Calender's personal injury claims and is therefore not viable without

those claims. We will therefore affirm the District Court's grant of summary judgment on the loss of consortium claim.

For the foregoing reasons, we will affirm the orders of the District Court.

III. Conclusion

All Citations

548 Fed.Appx. 761, Prod.Liab.Rep. (CCH) P 19,301

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TAB 10

2015 WL 2414740

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Kimberly COLE, Alan Cole, James Monica, Linda Boyd, Michael McMahon, Ray Sminkey, James Medders, Judy Medders, Robert Peperno, Sarah Peperno, and [Kelly McCoy](#), on behalf of themselves and all others similarly situated, Plaintiffs,

v.

NIBCO, INC., Defendant.

Civ. No. 3:13-cv-07871 (FLW)(TJB).

Signed May 20, 2015.

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OPINION

[WOLFSON](#), District Judge.

*1 Plaintiffs Kimberly Cole, Alan Cole, James Monica (“Monica”), Linda Boyd (“Boyd”), Michael McMahon (“McMahon”), Ray Sminkey (“Sminkey”), James Medders, Judy Medders, Robert Peperno, Sarah Peperno, and Kelly McCoy (“McCoy”) (collectively, “Plaintiffs”), who are nine homeowners from seven states, bring this putative class action on behalf of themselves and a nationwide class, or alternatively, putative New Jersey, Pennsylvania, Alabama, Georgia, Texas, Oklahoma, and Tennessee state subclasses. Presently before the Court is a partial motion to dismiss Plaintiffs’ Complaint filed by Defendant NIBCO, Inc.’s (“NIBCO” or “Defendant”), for failure to state a claim.

Plaintiffs’ claims stem from the alleged failures of various plumbing system products manufactured by NIBCO and installed in Plaintiffs’ homes. Plaintiffs allege that NIBCO breached an express warranty (Count I); breached the implied warranty of merchantability (Count II); breached the implied warranty of fitness for a particular purpose (Count III); was negligent in the design, testing, and manufacture of its products (Count IV); violated the New Jersey Consumer Fraud Act, [N.J. Stat. Ann. § 56:8-1 et seq.](#) (“NJCFA”) (Count V); violated the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Cons.Stat. Ann § 201-1, *et seq.* (“UTPCPL”) (Count VI); violated the Texas Deceptive Trade Practices Act, [Tex. Bus. & Com.Code Ann. § 17.41, et seq.](#) (“TDTPA”) (Count VII); violated the Oklahoma Deceptive Trade Practices Act, [Okla. Stat. Ann. tit. 78 § 51-55, et seq.](#) (“ODTPA”); and was unjustly enriched (Count IX). In Count X, Plaintiffs request declaratory relief and an injunction.

For the foregoing reasons, Defendant’s motion is GRANTED IN PART and DENIED IN PART. Counts II, III, and IV are dismissed as asserted by Monica, and Counts I, II, III, and IV are dismissed as asserted by the Coles; both sets of plaintiffs are granted leave to file claims under the NJPLA and the TPLA, respectively. Count I is dismissed without prejudice as asserted by McCoy. Counts I and II are dismissed without prejudice as asserted by McMahon. As asserted by all Plaintiffs, Counts III, IV, VI, VII, and VIII are dismissed without prejudice, and Counts V, IX, and X are dismissed. Count II as asserted by McCoy, however, may proceed.

I. FACTUAL BACKGROUND

The following factual allegations are taken from Plaintiffs’ Complaint and are accepted as true for the purposes of this motion to dismiss. See [Toys “R” Us, Inc. v. Step Two, S.A.](#), 318 F.3d 446, 457 (3d Cir.2003); [Dayhoff, Inc. v. H.J. Heinz Co.](#), 86 F.3d 1287, 1302 (3d Cir.1996). The Court need not recount all facts, and instead recounts only those relevant to the grounds asserted by Defendant in their motion.

This case concerns a putative class action by seven plaintiffs from six states, all of whom plead various causes of action proximately caused by defective plumbing system products manufactured by NIBCO, Inc., an Indiana corporation. FAC ¶¶ 9-13, 104. The three products at issue (collectively, “the PEX Products”) are: (1) cross-linked polyethylene plumbing tubes (“PEX Tubing”), (2) the brass fittings that connect PEX tubes together (“PEX Fittings”), (3) and stainless steel clamps (“PEX Clamps”) that join the PEX Tubes with the PEX

Fittings. *Id.* ¶¶ 1, 104. Plaintiffs allege that the PEX Products all suffer from design and/or manufacturing defects that allow water to escape their homes' plumbing systems and cause damage to both the PEX Products and the homes in which they are installed. *Id.* ¶¶ 9–12. Specifically, Plaintiffs allege that (1) the PEX Tubing "is prone to premature oxidative failure and creep rupture," (2) the PEX Fittings "are prone to dezincification corrosion," and (3) the PEX Clamps "are prone to failure b chloride-induced stress corrosion cracking." *Id.* 2–4.

*2 Plaintiffs allege that "NIBCO manufactures, warrants, advertises, and sells the PEX Products at issue and, further, that NIBCO's sales catalog advertised that, *inter alia*, its PEX tubing was the highest quality PEX tubing available, and that its cross chemical bonding process gave it 'superior characteristics.' " *Id.* ¶¶ 7–8. Plaintiffs further allege that NIBCO warrants that its PEX Tubing will be free from any defects in materials and workmanship ten years from the date of purchase when a licensed professional contractor installs the PEX Tubing. *Id.* ¶ 123. According to Plaintiffs, the warranty period for the PEX Tubing increases to twenty-five years when PEX Fittings and PEX Clamps are used in conjunction with the PEX Tubing. *Id.* at ¶ 121. However, "[c]ontrary to these affirmative statements, the PEX Products suffer from design and/or manufacturing defects." *Id.* ¶ 9. Plaintiffs allege that "NIBCO has systematically breached its warranty by failing to fully or adequately compensate property owners who have been injured as a result of the PEX Product Defects. NIBCO also failed to disclose this material information to Plaintiffs and Class Members." *Id.* ¶ 10. Further, Plaintiffs allege that "[b]efore manufacturing, warranting, advertising and/or selling the PEX Products, NIBCO failed to take appropriate steps to ensure that its products were safe for their intended use. [NIBCO] knew or should have known that the PEX Products were not suitable for use within water-carrying plumbing systems and that the PEX Products suffered from the PEX Product Defects." *Id.* ¶ 11.

Each Plaintiff's alleged injuries are detailed below.

a. The Coles, Tennessee Plaintiffs

In 2008, a licensed professional contractor installed a residential plumbing system in the new home of Kimberley Cole and Alan Cole (collectively, "the Coles"), Tennessee residents. FAC ¶¶ 14–15, 18. This system utilized all relevant PEX Products. *Id.* at ¶ 17. The Coles claim that failure of PEX Tubing caused several water leaks in their basement

between November 2010 and August 2014. *Id.* at ¶ 20–22. Upon discovery of the leaks, the Coles allegedly notified NIBCO of the PEX Tubing's failure, pursuant to the terms of NIBCO's express warranty for the PEX Products. *Id.* at ¶ 24. However, despite notice, Plaintiffs allege that NIBCO failed to honor the warranty by providing replacement products or other compensation. *Id.*

b. James Monica, New Jersey Plaintiff

In December 2010, a licensed professional contractor installed a residential plumbing system in the new home of James Monica, a New Jersey resident. FAC ¶¶ 28–29, 31. This system utilized all relevant PEX Products. *Id.* at ¶ 30. Monica claims that on three occasions, beginning in November 2012, PEX Fittings used in his home's plumbing system failed, causing "water saturation" on his basement's ceiling and walls and leaks in his first floor plumbing. *Id.* at ¶ 33–38. Upon discovery of the leaks, Monica allegedly notified NIBCO of the failure of the PEX Fittings, pursuant to the terms of NIBCO's express warranty of the PEX Products. *Id.* at ¶ 39. Plaintiffs allege that NIBCO failed to honor this express warranty, because replacement products or other compensation were never provided. *Id.* The FAC alleges that Monica's losses include not only the damaged PEX Fittings, but other "out-of-pocket loss associated with catastrophic plumbing failures and attempted repairs of such within his home." *Id.* at ¶ 42.

c. Linda Boyd, Alabama Plaintiff

*3 In June 2008, a licensed professional contractor installed a residential plumbing system in the new home of Linda Boyd, an Alabama resident. FAC ¶¶ 43–45, 47. This system utilized all relevant PEX Products. *Id.* at ¶ 46. Boyd claims that between March 26, 2013 and October 31, 2013, failure of PEX Tubing used in his home's plumbing system caused several water leaks. *Id.* at ¶ 49–51. Upon discovery of the leaks, Boyd allegedly notified NIBCO of the PEX Tubing's failure, pursuant to the terms of NIBCO's express warranty for the PEX Products. *Id.* at ¶ 53. As with the other Plaintiffs, Plaintiffs allege that NIBCO provided no relief to Boyd. *Id.*

d. Michael McMahon, Texas Plaintiff

Michael McMahon ("McMahon"), a Texas resident, moved into a home on January 1, 2013, that was constructed in 2007. FAC at ¶¶ 57–58, 61. When the home was constructed, licensed professional contractors installed a residential plumbing system that used all relevant PEX

Products. *Id.* at ¶ 59. Since 2013, McMahon has discovered six leaks in his home, all allegedly resulting from defects in PEX Tubing. *Id.* at ¶¶ 62–63. McMahon claims to have suffered “significant damages due to the PEX Product Defects,” including water saturation, flooding, and damage to his walls. *Id.* ¶ 64.

e. Ray Sminkey, Oklahoma Plaintiff

In spring 2008, a licensed professional contractor installed a residential plumbing system in the new home of Ray Sminkey (“Sminkey”), an Oklahoma resident. FAC 66–68, 70. This system utilized, in relevant part, only PEX Tubing. *Id.* at ¶ 69. Sminkey claims that beginning on November 5, 2013, the PEX Tubing used in his home’s plumbing system began to leak and had to be replaced by a plumber. *Id.* at ¶ 72–74. Sminkey claims to have suffered “significant damages on three separate occasions due to PEX Product Defects.” *Id.* ¶ 75.

f. The Medders, Texas Plaintiffs

In 2011, a licensed professional contractor installed a residential plumbing system in the new home of James and Judy Medders (collectively, “the Medders”), Texas residents. FAC ¶¶ 77, 79, 81. This system utilized all relevant PEX Products. *Id.* at ¶ 80. The Medders claim that the failures of various PEX Fittings caused leaks in various locations in their home between December 2013 and June 2014. *Id.* at ¶ 84–85. Upon discovery of the leaks, the Medders notified NIBCO of the problem, but allege that NIBCO failed to act under their express warranty and provide replacement PEX Fittings. *Id.* at ¶ 86.

g. The Pepernos, Pennsylvania Plaintiffs

In 2007, a licensed professional contractor installed a residential plumbing system in the new home of Robert and Sara Peperno (collectively, “the Pepernos”), Pennsylvania residents. FAC 90, 92, 94. This system utilized all relevant PEX Products. *Id.* at ¶ 93. The Pepernos claim that failure of the PEX Tubing caused three leaks in their basement between December 15, 2013 and June 7, 2014. *Id.* at ¶ 96–98. Upon discovery of the leaks, the Pepernos allegedly notified NIBCO of the failure of the PEX Tubing. However, NIBCO failed to act under their express warranty and provide replacement products or other compensation. *Id.* ¶ 100.

Kelly McCoy, Georgia Plaintiff

*4 In 2010, a licensed professional contractor installed a residential plumbing system in the new home of Kelly McCoy (“McCoy”), a Georgia resident. FAC ¶¶ 18:103–104, 19:106.¹ This system utilized all relevant PEX Products. *Id.* at ¶ 18:105. McCoy claims that the PEX Tubing used in his plumbing system failed repeatedly and caused leaks, which necessitated six separate repairs. *Id.* at ¶ 107. As a result of the leaks, the broken PEX Tubing had to be released and a bathroom wall needed to be repaired.

¹ The Court notes that the paragraph numbering convention used by Plaintiff in the FAC is erroneous on pages 18–20. See e.g., FAC at 18 (duplicate paragraph 103); *id.* at 19 (shift in numbering from 109 to 104). For clarity when citing to this portion of the record, a page number is provided along with the paragraph number.

Plaintiffs filed their Complaint in the District Court of New Jersey on December 27, 2013 and filed their First Amended Complaint (“FAC”) on October 6, 2014. Thereafter, Defendant filed the instant partial motion to dismiss. Defendant contends that nearly all of the causes of action asserted in the FAC fail to state a claim.

II. STANDARD OF REVIEW

When reviewing a motion to dismiss on the pleadings, courts “accept all factual allegations as true, construe the FAC in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the FAC, the plaintiff may be entitled to relief.” *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir.2008) (citation and quotations omitted). In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the Rule 12(b)(6) standard: the factual allegations set forth in a complaint “must be enough to raise a right to relief above the speculative level.” *Id.* at 555. As the Third Circuit has stated, “[t]he Supreme Court’s *Twombly* formulation of the pleading standard can be summed up thus: ‘stating ... [a] claim requires a complaint with enough factual matter (taken as true) to suggest’ the required element. This ‘does not impose a probability requirement at the pleading stage,’ but instead ‘simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element.’” *Phillips*, 515 F.3d at 234 (quoting *Twombly*, 127 U.S. at 555); *see also Covington v. Int’l Ass’n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir.2013) (“[A] claimant does not have to set out in detail the facts upon which he bases his claim. The pleading standard is

not akin to a probability requirement; to survive a motion to dismiss, a complaint merely has to state a plausible claim for relief.” (citations omitted)).

In affirming that *Twombly*’s standards apply to all motions to dismiss, the Supreme Court explained several principles. First, “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). Second, “only a complaint that states a plausible claim for relief survives a motion to dismiss.” *Id.* at 679. Therefore, “a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth.” *Id.* Ultimately, “a complaint must do more than allege the plaintiffs entitlement to relief. A complaint has to ‘show’ such an entitlement with its facts.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir.2009). However, “a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings ... [although a] limited exception exists for documents that are integral to or explicitly relied upon in the FAC.” *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 97 n. 6 (3d Cir.2010) cert. denied, 132 S.Ct. 98 (2011) (citation and internal quotation marks omitted).

*5 The Third Circuit has reiterated that “judging the sufficiency of a pleading is a contextdependent exercise” and “[s]ome claims require more factual explication than others to state a plausible claim for relief.” *Id.* at 98. That said, the Rule 8 pleading standard is applied “with the same level of rigor in all civil actions.” *Id.* (quoting *Iqbal*, 556 U.S. at 684).

III. DISCUSSION

At the outset, the Court notes that Plaintiffs indicate under which state’s law they have brought suit in only four of their asserted ten Counts: Counts V, VI, VII, and VII, alleging respective violations of the consumer fraud statutes of New Jersey, Pennsylvania, Texas, and Oklahoma. By contrast, Plaintiffs’ asserted claims for breach of express warranty (Count I), breach of implied warranties of fitness for a particular purpose and merchantability (Counts II and III), negligence (Count IV), and unjust enrichment (Count IX) are devoid of reference to any particular state’s laws. *See* FAC ¶¶ 144–73, 208–12. However, Defendant suggests, and Plaintiffs do not dispute, that the state law of each Plaintiff’s home state should apply to Plaintiffs’ claims. Def.’s Br. at 9 n. 5; Pls.’ Opp. Br. at 13 n. 7. Therefore, the Court will follow the lead of

the parties and will not engage in a choice of law analysis.² *See, e.g., UBI Telecom Inc. v. KDDI Am., Inc.*, No. CIV.A. 13–1643 KSH, 2014 WL 2965705, at *9 (D.N.J. June 30, 2014) (“When the parties agree upon which state’s law applies ... the Court need not conduct [a] choice-of-law inquiry.”); *see also MacDonald v. Unisys Corp.*, 951 F.Supp.2d 729, 737 & n. 5 (E.D.Pa.2013) (Brody, J.); *Sager v. Hoffman La Roche, Inc.*, 2012 WL 3166630, at *14 n. 9 (N.J.Super.Ct., App.Div. Aug. 7, 2012) (per curiam).

² The Court notes that, although Defendant does not raise the issue, the FAC’s failure to specify which state’s laws apply to their common law claims may not meet the Rule 8 pleading standard. *See, e.g., In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 167 (E.D.Pa.2009) (“The plaintiffs fail to link their claim to the law of any particular state. As a result of this deficiency, the plaintiffs fail to state a cause of action”); *see also Nimley v. PTT Phone Cards Inc.*, No. CIV.A. 13–2216, 2014 WL 1464311, at *6 n. 7 (E.D.Pa. Apr.15, 2014). However, out of an abundance of caution, the Court will proceed by analyzing Defendant’s arguments on the merits of the FAC, particularly because the parties appear to be in agreement that each Plaintiff’s home state laws apply to each common law cause of action.

a. Subsumption of Tort, Warranty, and Consumer Fraud Claims for New Jersey and Tennessee Plaintiffs

Defendant argues that the tort, implied warranty, and consumer fraud claims asserted by Monica and the tort and warranty claims asserted by the Coles “unquestionably” constitute “product[s] liability action[s],” and, thus, are subsumed by the New Jersey Products Liability Act (“NJPLA”) and the Tennessee Products Liability Act (“TPLA”), respectively. Def.’s Br. at 9–10.

Plaintiffs counter that the NJPLA’s plain language is insufficient to determine if the NJPLA subsumes Monica’s claim and that the TPLA does not subsume claims for damages arising from products that are “merely ineffectual,” as opposed to dangerous. Pls.’ Opp. Br. at 17 (citing *Lincoln Gen. Ins. Co. v. Detroit Diesel Corp.*, 293 S.W.3d 487 (Tenn.2009)).

i. Monica (New Jersey)

The Court will begin by examining whether the NJPLA subsumes Monica’s claims. The NJPLA was enacted “to limit

the expansion of products-liability law” and “to limit the liability of manufacturers so as to balance[] the interests of the public and the individual with a view towards economic reality.” *Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34, 47–48, 675 A.2d 620 (1996) (quotations and citations omitted). The NJPLA, therefore, “established the sole method to prosecute a product liability action[,]” and after its enactment, “only a single product liability action remains.” *Tirrell v. Navistar Int'l, Inc.*, 248 N.J.Super. 390, 398–99, 591 A.2d 643, (N.J.Super.Ct.App.Div.1991); *see also Repola v. Morbark Industries, Inc.*, 934 F.2d 483, 492 (3d Cir.1991) (explaining that the NJPLA “effectively creates an exclusive statutory cause of action for claims falling within its purview”). The NJPLA provides that “products liability actions” are “any claim[s] or action[s] brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim.” N.J. Stat. Ann. § 2A:58C-1(b) (3); *see U-Line Corp.*, No. 13–3203, 2013 WL 5503672, at *9. Therefore, if any of Plaintiff's claims are subsumed under the NJPLA, they will be dismissed.³ *See, e.g., McDonough v. Bayer Healthcare, LLC*, No. CIV. 10–442, 2011 WL 2119107, at *3 (D.N.J. May 26, 2011).

³ Claims for breach of express warranty are specifically not subsumed by the NJPLA. N.J. STAT. ANN. 2A:58C-1(b)(3) (defining “products liability action” as “any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty.”).

^{*6} Indeed, courts have dismissed breach of implied warranty, NJCFA consumer fraud, unjust enrichment, and negligence claims—the claims asserted by Monica in Counts II, III, IV, V, and IX the FAC—based on NJPLA subsumption. *See Certain Underwriters at Lloyd's, London v. U-Line Corp.*, No. 13–3203, 2013 WL 5503672, at *4–5 (D.N.J. Oct.1, 2013) (dismissing negligence claims and implied warranty claims); *Smith v. Merial Ltd.*, No. 10–439, 2011 WL 2119100, at *5 (D.N.J. May 26, 2011) (dismissing NJCFA consumer fraud and unjust enrichment claims).

However, the NJPLA's reach is limited in one significant respect: the statute excludes any causes of action arising out of a harm solely to the defective product. N.J. Stat. Ann. § 2A:58C-1b(2); *see also Estate of Knoster v. Ford Motor Co.*, No. 01–3168, 2008 U.S. Dist. LEXIS 103342, at *14 n. 4, 2008 WL 5416399 (D.N.J. Dec. 22, 2008) (holding that

“economic damages for destruction of the product are not recoverable under the NJPLA”). In order to ascertain whether the NJPLA subsumes a claim in which damage as a result of a defective product is alleged, the Court must determine the type of harm the Plaintiff is alleging: whether the harm includes property damage caused by the PEX Product or whether the harm was solely to the defective PEX Product itself.⁴ *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 66, 948 A.2d 587 (N.J.2008) (“The language of the PLA represents a clear legislative intent that ... the PLA is paramount when the underlying claim is one for harm caused by a product.”); *see also Arlandson v. Hartz Mountain Corp.*, 792 F.Supp.2d 691, 703 (D.N.J.2011) (“[R]egardless of how a claim is pleaded, where the core issue is the harmfulness of the product's chemicals, the claim must be pleaded as an NJPLA claim.”).

⁴ I note that Plaintiffs rely on a case in this district which found that the NJPLA does not subsume claims for damages consequentially caused by a defective product. *See Kuzian v. Electrolux Home Prods.*, 937 F.Supp.2d 599, 607–08 (D.N.J.2013). The facts of this case are very similar to the instant case: both concern an allegedly defective product that malfunctioned, broke, and caused water damage. *Id.* at 604–05. The plaintiff in *Kuzian* asserted various breaches of warranty and fraud claims, and those claims were determined to not have been subsumed by the NJPLA. *Id.* at 607–08. Plaintiffs analogize the instant case to the *Kuzian* case and argue that the NJPLA should similarly decline to subsume Plaintiffs' claims. Plaintiffs assert that, like the plaintiff in *Kuzian*, they have alleged harm to the product itself and consequential damage to Plaintiffs' property. However, the Court does not find this reasoning persuasive. *Kuzian* contradicts other cases in this district that have discussed this issue. *Montich v. Miele USA, Inc.*, 849 F.Supp.2d 439, 456–57 (D.N.J.2012) (a complaint alleging harm caused by a defective product would be subsumed by the NJPLA); *U-Line Corp.*, No. 13–3203, 2013 WL 5503672, at *4–5 (rejecting *Kuzian*). Further, tellingly, the *Kuzian* Court granted reconsideration of its decision on this very issue. *Kuzian v. Electrolux Home Prods.*, No. 12–3341(NLH), 2013 WL 6865083 at *1 (D.N.J. Dec.30, 2013) (“finding after review of the submissions that it should re-examine the issue of whether plaintiffs' claims concerning the damages caused by the allegedly

faulty ice makers to property other than the product itself, e.g., food, floors and walls are consequential, economic losses, but rather sound in tort and are subsumed by the NJPLA").

Here, it is clear from Plaintiffs' factual allegations that Monica's claims all sound in products liability and, moreover, that the harm alleged is not solely harm to the PEX Products themselves. Monica alleges that the PEX Fittings used in the construction of his home suffered from inherent design flaws. When the PEX Fittings failed, severe "water saturation" resulted. FAC at ¶ 33. The FAC specifically indicates that Monica's losses included both the destroyed PEX Fittings, as well as "loss associated with [the] catastrophic plumbing failure[]." *Id.* at ¶ 41. The FAC makes clear, then, that the physical replacement of the broken PEX Fittings or Monica's the inability to use the PEX Fittings is not the thrust of Monica's injury. Instead, the injury primarily consists of the "catastrophic plumbing failure" that caused damage and water saturation throughout his home. *Id.* at ¶¶ 33, 41. As Monica's true harm is not to the product itself, his claims fall within the ambit of the NJPLA. *See Arlandson v. Hartz Mountain Corp.*, 792 F.Supp.2d 691, 703 (D.N.J.2011). For this reason, Monica's tort and implied warranty claims, in Counts II, III, and IV, are subsumed by the NJPLA. Monica's claim under the New Jersey Consumer Fraud Act, ("NJCFA"), in Count V, is also subsumed by the NJPLA.⁵ Accordingly, Counts II, III, IV, and V as asserted by Monica, are dismissed. However, Monica is given leave to re-plead his claims as a single claim under the NJPLA.

⁵ Plaintiffs argue that Monica's NJCFA claim cannot be subsumed by the NJPLA. But Defendant is correct: "there is no exception for NJCFA claims where, as here, the gravamen of the claim is that the challenged statements or omissions led to harm that falls within the scope of the NJPLA." Def.'s Reply Br. at 12; *see Sun Chem. Corp. v. Fike Corp.*, No. CIV. 13-4069 FSH, 2015 WL 881961, at *3 (D.N.J. Mar.2, 2015) (collecting cases); *Indian Brand Farms v. Novartis Crop Prot., Inc.*, 890 F.Supp.3d 524, 547-48; *McDarby v. Merk & Co.*, 401 N.J.Super. 10, 949 A.2d 223, 277-78 (N.J.Super.Ct.App.Div.2008).

ii. The Coles (Tennessee)

*7 Next, the Court examines whether the Coles' claims are subsumed by the TPLA. As the Sixth Circuit has noted,

[T]he TPLA governs products liability actions in Tennessee and defines "product liability actions" as "all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packing, or labeling of any product." The TPLA also encompasses several different theories of products liability: "strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent or innocent; or under any other substantive legal theory in tort or contract whatsoever.

Strayhorn v. Wyeth Pharm., Inc., 737 F.3d 378, 392 (6th Cir.2013) (internal citation and quotation marks omitted). "The TPLA's definition of 'product liability action' has been interpreted broadly." *Id.* at 402.

Here, just as with Monica's claims, the Coles' claims clearly sound in products liability by alleging property damage caused by or resulting from the manufacture, design, and marketing of the PEX Products. Plaintiffs' argument that the Coles merely assert "economic loss" is inapposite: the "economic loss" doctrine relates to the interplay between tort and contract law and has no place in this analysis, which is solely focused on whether Plaintiffs' claims are subsumed by the TPLA. *See Lincoln Gen. Ins. Co. v. Detroit Diesel Corp.*, 293 S.W.3d 487, 488 (Tenn.2009); the Coles clearly allege property damage in the form of "water saturation and damage throughout their home." FAC ¶¶ 22. Therefore, Coles' claims in Counts I,⁶ II, III, and IV are dismissed. However, the Coles are given leave to re-plead their claims as a single claim under the TPLA.

⁶ Unlike the NJPLA, the TPLA subsumes claims for breach of an express warranty. *Strayhorn*, 737 F.3d at 392. Therefore, unlike for Monica, the Coles' claim of breach of express warranty in Count I is dismissed.

b. Counts I and II—Express Warranty and Implied Warranty of Merchantability Claims—McMahon (Texas) and McCoy (Georgia)

Defendants next argue that McMahon and McCoy fail to state claims for breach of an express warranty and breach of the implied warranty of merchantability because they "have not

fulfilled their contractual and legal duties to provide pre-suit notice of a failure and a demand for a replacement under the warranty.” Def.’s Br. at 13. Specifically, Defendants argue that Texas and Georgia, the home states of McMahon and McCoy, respectively, require pre-suit notice of the breach and a request for a remedy as conditions precedent to asserting express and implied warranty claims under those state’s laws.

NIBCO’s express warranty, attached to the FAC, states that “[i]n the event that any defect occurs which the owner believes is covered by this warranty, the owner should immediately contact NIBCO Technical Services, either in writing or by telephone ... The owner will then be instructed to return said [product], at the owner’s expense, to NIBCO.... In the event said inspection discloses to the satisfaction of NIBCO ... that said [product] is defective, a replacement shall be mailed free of charge to the owner.” NIBCO Warranty.

***8** Neither McMahon nor McCoy allege that they contacted NIBCO about any of the alleged defective PEX Products prior to filing this suit.⁷ Both Georgia and Texas laws regarding the breach of the implied warranty of merchantability are taken from the same UCC provision. That provision states that “[t]he buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy.” Ga.Code Ann. § 11-2-607; Tex. Bus. & Com.Code Ann. § 2.607.

⁷ Unlike McMahon, the Medders, the other Texas plaintiffs, alleged that “[w]ithin a reasonable amount of time following the losses, the Medders provided NIBCO with actual notice of the failures of its PEX Products and NIBCO failed to replace the PEX Products within the Medders’ home or otherwise fulfill its warranty obligations.” FAC ¶ 86.

1. McMahon (Texas)

“To recover on a breach of warranty claim in Texas, ‘the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy.’” *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 705 (5th Cir.2014) (citing Tex. Bus. & Com.Code § 2.607(c)(1)). Texas law applies Tex. Bus. & Com.Code Ann. § 2.607 to breach of express warranty and breach of implied warranty claims, and “‘commencement of litigation’ does not satisfy the notice requirement” for either express or implied warranty claims. See *McKay*, 751 F.3d at 706.

“Although the Texas Supreme Court has not decided [the] issue of [whether notice must be given to a remote manufacturer or seller to satisfy § 2.607’s requirements], the weight of intermediate Texas authority interprets the applicable version of § 2.607 to require” such notice. *Id.* at 707. The Texas appellate case that Plaintiffs cite for the opposite proposition, *Vintage Homes, Inc. v. Coldiron*, 585 S.W.2d 886, 888–89 (Tex.Civ.App.-El Paso 1979, no writ), interpreted a prior version of the statute at issue and goes against the clear majority of the Texas appellate courts that have considered the issue. See, e.g., *Bailey v. Smith*, No. 13-05-085-CV, 2006 WL 1360846, at *4–5 (Tex.App.-Corpus Christi May 18, 2006, no pet.); *U.S. Tire-Tech, Inc. v. Boeran, B. V.*, 110 S.W.3d 194, 199 (Tex.App.-Houston [1st Dist.] 2003, pet. denied); *Wilcox v. Hillcrest Memorial Park of Dall.*, 696 S.W.2d 423, 424 (Tex.App.-Dallas 1985, writ ref’d n.r.e).

McMahon does not allege that he provided pre-suit notice to Defendant before bringing his breach of warranty claims, as required under Texas law. Thus, his breach of express warranty and breach of the implied warranty of merchantability claims, asserted in Counts I and II, are dismissed without prejudice. See, e.g. *Martin v. Home Depot U.S.A., Inc.*, 369 F.Supp.2d 887, 893 (W.D.Tex.2005).

2. McCoy (Georgia)

Georgia courts analyze breach of written, or express, warranty and breach of implied warranty claims differently; accordingly, the Court will do the same. “Georgia law imposes two conditions before a breach of a written warranty can exist: (1) notice of the defect and (2) a reasonable opportunity to repair the defect.” *Knight v. Am. Suzuki Motor Corp.*, 272 Ga.App. 319, 321–22, 612 S.E.2d 546 (2005). Accordingly, a warranty is not breached simply because a vehicle is found “on delivery or at some time thereafter within the warranty period to have a defective part or [an] operational deficiency.” *Id.* (citing *Olson v. Ford Motor Co.*, 258 Ga.App. 848, 575 S.E.2d 743 (Ga.App.2002) (citation and footnote omitted)). “Assuming the purchaser has maintained his vehicle in the manner specified, it is the *refusal to remedy* within a reasonable time, or a *lack of success* in the attempts to remedy [that] would constitute a breach of warranty.” *Id.* (citing *Olson*, 258 Ga.App. 848, 575 S.E.2d 743; *Culberson v. Mercedes-Benz USA, Ltd.*, 274 Ga.App. 89, 91, 616 S.E.2d 865 (2005) (“When a warrantee brings a breach of express warranty claim, the terms of the written warranty control. Thus, a warrantee can succeed on a breach of the warranty claim only if she has first satisfied the express

conditions precedent for enforcement “as prescribed” by the warranty”).

*9 Here, because McCoy has not pleaded that he provided notice or a reasonable opportunity to repair the allegedly defective PEX products to Defendant, pursuant to the terms of the warranty, his breach of an express warranty claim must fail. *See, e.g., id.* Accordingly, Count I as asserted by McCoy is dismissed without prejudice.

The Court now turns to McCoy's implied warranty of merchantability claim. The Georgia Court of Appeals has found that “delay alone [in providing reasonable notice to the seller] without prejudice caused by such delay is insufficient to bar relief to the plaintiff” under Georgia's statute pertaining to the breach of the implied warranty of merchantability. *Wal-Mart Stores, Inc. v. Wheeler*, 262 Ga.App. 607, 608, 586 S.E.2d 83 (2003) (analyzing a situation in which the plaintiff had only provided notice to Wal-Mart upon filing a lawsuit, two years after the breach allegedly took place). Thus, the reasonable notice inquiry under Georgia law turns on whether the defendant has demonstrated prejudice as a result in the delayed notice.

Here, the Court lacks the requisite facts at the motion to dismiss stage to determine whether filing this lawsuit constitutes reasonable notice of McCoy's breach of the implied warranty of merchantability claim. Accordingly, the Court declines to dismiss Count II as asserted by McCoy. *See, e.g., In re Ford Motor Co. E-350 Van Products Liab. Litig. (No. II)*, No. CIV. A. 03-4558, 2010 WL 2813788, at *34 (D.N.J. July 9, 2010) amended, No. CIV.A. 03-4558 GEB, 2011 WL 601279 (D.N.J. Feb.16, 2011) (applying Georgia law regarding reasonable notice of breach of warranty claims on a motion for summary judgment); *see also Terrill v. Electrolux Home Prods.*, 753 F.Supp.2d 1272, 1287, (S.D.Ga.2010).

c. Count III—Implied Warranty of Fitness

Next, Defendant argues that “[e]ach Plaintiff's claim for breach of the implied warranty of fitness for a particular purpose (Count III) fails because Plaintiffs used the PEX products for their ordinary purpose in residential plumbing systems and have failed to plead the requirements of a particular purpose claim” Def.'s Reply Br. at 3. Plaintiffs, however, claim that a “particular” purpose and an “ordinary” purpose are not mutually exclusive. Pls.' Opp. Br. at 13.

While Plaintiffs assert breach of implied warranty of fitness claims under various states' laws, it does appear that all of the states mentioned require that the product at issue be used for a “particular” purpose in order for a plaintiff to raise such a claim.⁸ All of the relevant states utilize the following Uniform Sales Act provision to define a breach of the implied warranty of fitness:

8

See Tex. Bus. & Com.Code Ann. § 2.315 cmt. 2; Okla. Stat. Ann. Tit. 12A, § 2-315 cmt. 2; Ga.Code Ann. § 11-2-315 cmt. 2; Tenn.Code Ann. § 47-2-315 cmt. 2; N.J.S.A. § 12A:2-315 cmt. 2; Ala.Code § 7-2-315 cmt. 2; 13 Pa. Cons.Stat. Ann. § 2315 cmt. 2.

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.

*10 *Tex. Bus. & Com.Code Ann. § 2.315; Okla. Stat. Ann. Tit. 12A, § 2-315; Ga.Code Ann. § 11-2-315; Tenn.Code Ann. § 47-2-315; N.J.S.A. § 12A:2-315; Ala.Code § 7-2-315; 13 Pa. Cons.Stat. Ann. § 2315.*

In a comment regarding the most recent iteration of the provision, it is noted that

A “particular purpose” differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question. For example, shoes are generally used for the purpose of walking upon ordinary ground, but a seller may know that a particular pair was selected to be used for climbing mountains.

Id. cmt. 2. The FAC merely alleges that the PEX products, which are ordinarily used in the course of installing a

plumbing system, were used as such by Plaintiffs, and Plaintiffs concede as much in their opposition brief. However, Plaintiffs argue that the ordinary purpose was a particular purpose in that NIBCO advertised its PEX products as containing “superior characteristics,” making them “the highest quality PEX tubing available today ... In other words, PEX products are not only good for getting around town, they will help you climb a mountain.” Pls.’ Br. at 14.

Plaintiffs’ argument is unconvincing. The cases to which Plaintiffs cite (to the extent they are relevant, as the cited cases regard laws of states that are not at issue here) do not support Plaintiffs’ position that “ordinary purpose” and “particular purpose” need not be mutually exclusive; they state that a product can be used for *both* an ordinary and a particular purpose, not that an ordinary purpose can be the same as a particular purpose. *See, e.g., Palmer v. A.H. Robins Co.*, 684 P.2d 187, 208–09 (Col. 1984); *Gregory Woods Prods. v. Advanced Sawmill Mach. Equip., Inc.*, 2007 U.S. Dist. LEXIS 46245, 2007 WL 1825179 (W.D.N.C.2007). Further, Plaintiffs do not plead any facts in their Amended Complaint to show that Defendant had any reason to know that the PEX products were to be used by Plaintiffs for a particular purpose. *See generally* FAC. Therefore, Plaintiffs’ implied warranty of particular fitness claim in Count III is dismissed without prejudice.

d. Count IV–Negligence

Next, Defendants argue that Plaintiffs’ negligence claims must be dismissed.⁹

⁹ The Court has already dismissed the negligence claims of Monica and the Coles as subsumed under those plaintiffs’ respective state products liability acts. *See supra* Section III.a.

The FAC states that “Defendant owed Plaintiffs ... a duty to exercise reasonable and ordinary care in the formulation, testing, design, manufacture, warranting and marketing of the PEX Products.” Further, “[t]he failure of the PEX Products ... was caused by poor and improper workmanship and manufacture, negligence, and lack of reasonable and ordinary care by NIBCO.... Defendant failed to properly test and/or evaluate the PEX Products to ensure they would not fail when they were used for their intended purpose.” Finally, “[a]fter being notified of the foregoing breaches, NIBCO took no action to cure its breaches of its duty ... As a direct and proximate result of NIBCO’s negligence ... Plaintiffs ... have

been caused to suffer losses and damages ...” FAC ¶¶ 169–172.

*11 This laundry list of duties that Defendant allegedly breached does not suffice for asserting a negligence claim, particularly for asserting separate negligence claims under Plaintiffs’ respective home states. Each state’s negligence jurisprudence varies; for example, Texas courts appear to have found that where the gravamen of a plaintiff’s claim sounds in products liability, a plaintiff’s general negligence claim may not be permitted. *See Ford Motor Co. v. Miles*, 141 S.W.3d 309, 315 (Tex.App.2004). However, Pennsylvania law appears to allow for such claims, *see, e.g., Scilvio v. Amgen, Inc.*, 810 F.Supp.2d 745, 755 (W.D.Pa.2011). Plaintiffs do not adequately specify how their allegations meet the elements of each relevant state’s conception of negligence, and, as such, Count IV must be dismissed without prejudice for failure to state a claim.¹⁰ *See, e.g., In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 167 (E.D.Pa.2009); *see also Nimley v. PTT Phone Cards Inc.*, No. CIV. A. 13–2216, 2014 WL 1464311, at *6 (E.D.Pa. Apr.15, 2014).

¹⁰ Defendant argues that under the “gist of the action” doctrine, Plaintiffs’ negligence claims are really breach of warranty claims and, as such, should be dismissed. However, a review of Count IV reveals that Plaintiffs’ Count IV’s allegations go beyond the scope of breach of warranty. *See* FAC ¶¶ 169–172.

e. Counts V, VI, VII, and VIII–Statutory Consumer Fraud Claims

Next, Defendants argue that the New Jersey, Pennsylvania, Texas, and Oklahoma statutory consumer fraud claims, asserted in Counts V, VI, VII, and VIII, respectively,¹¹ should be dismissed for failure to state a claim.

¹¹ Specifically, Plaintiffs assert claims under the NJCFA, the Pennsylvania Unfair Trade Practices and Consumer Protection Law (the “UTPCPL”), the Texas Deceptive Trade Practices Act (“TDTPA”), and the Oklahoma Consumer Deceptive Trade Practices Act (“ODTPA”).

“Independent of the standard applicable to Rule 12(b)(6) motions,” *Rule 9(b) of the Federal Rules of Civil Procedure* requires a heightened pleading standard for claims sounding in fraud or mistake. *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir.2002); *see also* Fed.R.Civ.P. 9(b) (“In alleging fraud or mistake, a party

must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.”). All of the relevant consumer fraud claims are governed by Rule 9(b)'s heightened pleading requirements. *Crozier v. Johnson & Johnson Consumer Cos.*, 901 F.Supp.2d 494, 506 (D.N.J.2012) (analyzing the NJCFA); *Post v. Liberty Mut. Grp., Inc.*, Civ. No. 14-CV-238, 2014 WL 2777385, at *2–4 (E.D. Pa. June 18, 2014) (analyzing the UTPCPL); *Berry v. Indianapolis Ins. Co.*, 608 F.Supp.3d 785, 800 (N.D.Tex.2009) (analyzing the TDTPA).

The Third Circuit has adopted a flexible approach for evaluating whether a plaintiffs fraud claim meets Rule 9(b)'s heightened pleading standard. *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir.1984) (“Rule 9(b) requires plaintiffs to plead with particularity the ‘circumstances’ of the alleged fraud.... It is certainly true that allegations of ‘date, place or time’ [suffice], but nothing in the rule requires them. Plaintiffs are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud.”); *see also Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir.2007) (“Pursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the ‘precise misconduct with which it is charged.’ ” (quoting *Lum v. Bank of America*, 361 F.3d 217, 223–24 (3d Cir.2004)).

i. Count V—Monica's NJCFA Claim

*12 The Court decided *supra* that Monica's NJCFA claim sounded in product liability, and, as such, dismissed Count V as being subsumed by the NJPLA. Accordingly, the Court need not engage in further analysis of Count V.

ii. Count VI—The Pepernos' UTPCPL Claim

“The UTPCPL generally prohibits unfair methods of competition and deceptive acts or practices in the conduct of trade or commerce.” *Slapikas v. First Am. Title Ins. Co.*, 298 F.R.D. 285, 292 (W.D.Pa.2014) (citing 73 Pa. Stat. § 201–3); *see also Gardner v. State Farm Fire & Casualty Co.*, 544 F.3d 553, 564 (3d Cir.2008). “The UTPCPL lists twenty specifically prohibited practices in § 201–2(4)(i)–(xx), and also contains a catch-all provision.” *Garczynski v. Countrywide Home Loans, Inc.*, 656 F.Supp.2d 505, 509 (E.D.Pa.2009). The catchall provision provides a “private right of action in persons upon whom unfair methods of competition and unfair or deceptive acts or practices are

employed and who, as a result, sustain an ascertainable loss.” 73 Pa. Stat. § 201–9.2; *Slapikas*, 298 F.R.D. at 292.

“To establish liability under the UTPCPL's catchall provision a plaintiff must present evidence showing: (1) a deceptive act that is likely to deceive a consumer acting reasonably under similar circumstances; (2) justifiable reliance; and (3) that the plaintiffs justifiable reliance caused ascertainable loss.” *Slapikas*, 298 F.R.D. at 292 (citing *Seldon v. Home Loan Servs.*, 647 F.Supp.2d 451, 470 (E.D.Pa.2009); *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 223 (3d Cir.2008), as amended (Nov. 6, 2008)).

Defendants argue that the Pepernos fail to state a claim under the UTPCPL because they (1) do not identify a deceptive act with requisite specificity and (2) do not allege justifiable reliance.

The FAC states that

Defendant has engaged in deceptive business practices prohibited by the UTPCPL, including (1) representing that the PEX Products have characteristics, use, benefits, and qualities which they do not have, (2) representing that PEX Products are of a particular standard, quality, and grade when they are not, (3) advertising the PEX Products with the intent not to sell them as advertised, and (4) engaging in acts and practices which are otherwise unfair, misleading, false, or deceptive to the consumer.

FAC ¶ 186. While the FAC further states that “NIBCO's unfair or deceptive practices were likely to and did in fact deceive reasonable consumers, including the Pepernos, about the true performance and characteristic of the PEX Products,” FAC 187, the Pepernos include no specific factual allegations stating that they chose to have PEX Products installed in their home because of Defendant's allegedly deceptive business practices, let alone factual allegations about when, where, and how they were exposed to Defendant's allegedly deceptive practices. *See* FAC ¶¶ 90–103. Therefore, regardless of whether Pepernos have adequately alleged that NIBCO

engaged in deceptive business practices, presumably by advertising their products were of high quality, their UTPCPL claim fails because they do not allege justifiable reliance on such practices. *See, e.g., Kee v. Zimmer, Inc.*, 871 F.Supp.2d 405, 412 (E.D.Pa.2012); *see also Militello v. Allstate Prop. & Cas. Ins. Co.*, 2014 WL 2892386, at *4 (M.D.Pa. June 26, 2014) (“Plaintiff’s UTPCPL claim ... lacks supporting factual allegations demonstrating that Plaintiff justifiably relied on Defendant’s representations or conduct”). Accordingly, Count VI is dismissed without prejudice.

i. Count VII—McMahon and the Medders’ TDTPA Claim

*13 The TDTPA “grants consumers a cause of action for false, misleading, or deceptive acts or practices.” *Amstadt v. U.S. Brass Corp.*, 919 S.W.2d 644, 649 (Tex.1996); *see also Tex. Bus. & Com Code Ann. § 17.50(a)(1)* (2009). “The elements of a DTPA cause of action are: (1) the plaintiff is a consumer; (2) the defendant committed acts ‘in connection with the purchase or lease of any goods or services’; (3) the defendant’s acts were false, misleading or deceptive; and (4) the acts were a producing cause of plaintiff’s injuries.” *Cushman v. GC Servs., LP*, 657 F.Supp.2d 834, 842 (S.D.Tex.2009) *aff’d sub nom. Cushman v. GC Servs., L.P.*, 397 Fed. App’x 24 (5th Cir.2010) (quoting *Amstadt*, 919 S.W.2d at 649); *see also Washington v. U.S. HUD*, 953 F.Supp. 762, 777 (N.D.Tex.1996). “A producing cause is synonymous with natural result and has been defined as an efficient, exciting or contributing cause that, in a natural sequence, produced the complained of injuries or damages.” *McClung v. Wal-Mart*, 866 F.Supp. 306, 310 (N.D.Tex.1994).

Defendants argue that the Texas plaintiffs do not allege with requisite particularity (1) the allegedly unlawful acts in which Defendant engaged under the TDTPA, and (2) that any such acts caused their injuries.

In the FAC, Plaintiffs allege that “NIBCO’s actions as set forth above occurred in the conduct of trade or commerce, and constitute deceptive trade practices under the TDTPA” and that “[a]ll procedural requisites, including notice, have been met.” FAC ¶¶ 194, 196. Further, “[a] causal relationship exists between Defendant’s unlawful, false, deceptive, and misleading conduct and Plaintiffs’ and Texas Class members’ injuries.... Had Defendant not engaged in the aforementioned deceptive conduct, Plaintiffs and the Texas Class would not have purchased and installed Defendant’s PEX Products in their residential and commercial properties.” FAC ¶ 198.

However, similar to the Pepernos, the Texas Plaintiffs do not provide factual allegations in support of their conclusory statement that Defendant’s allegedly false, deceptive, or misleading conduct was a producing cause of Plaintiff’s injuries. The Medders and McMahon merely state that their residential plumbing system was installed using NIBCO PEX Products and conclusorily allege that “a causal relationship exists” between Defendant’s conduct and their damages—they provide no specificity about any false, misleading, or deceptive statements or actions by Defendants and how such behavior would constitute a “producing cause” of their decision to install PEX Products in their home. FAC ¶¶ 59, 80. Therefore, regardless of whether Plaintiffs have identified allegedly false, misleading, or deceptive behavior on the part of Defendant, their claim fails on the TDTPA’s causal element. *See, e.g., Robinson v. Match.com, L.L.C.*, No. 3:10-CV-2651-L, 2012 WL 5007777, at *10 (N.D.Tex. Oct.17, 2012) *aff’d sub nom. Malsom v. Match.com, L.L.C.*, 540 Fed. App’x 412 (5th Cir.2013). Accordingly, Count VI is dismissed without prejudice.

ii. Count VIII—Sminkey’s ODTPA Claim

*14 Regarding Plaintiff’s Sminkey’s fraud claim under the ODTPA, Sminkey acknowledges in Plaintiff’s opposition brief that the Oklahoma Deceptive Trade Practices Act does not create a private right of action for consumers, *see Thomas v. Metro. Life Ins. Co.*, 540 F.Supp.2d 1212, 1228 (W.D. Okla. Jan 10, 2008), and seeks leave to re-plead his claim under the Oklahoma Consumer Protection Act (“OCPA”). Pl.’s Opp. Br. at 27. As such, Count VIII is dismissed without prejudice.

f. Count IX—Unjust Enrichment

Defendants next argue that Plaintiffs’ unjust enrichment claims must fail for one of two reasons. First, the unjust enrichment claims asserted by McCoy, McMahon, the Medders, Boyd, and the Coles must fail, because “under the laws of their respective states, Plaintiff[s] ... cannot maintain their unjust enrichment claim ... because they allege the existence of an actual contract (the express warranty) governing their relationship” with Defendant. Def.’s Br. at 27. Second, Defendants argue that the unjust enrichment claims asserted by Boyd, Monica, and the Pepernos fail “because their home states do not recognize a claim for unjust enrichment against defendants from whom the plaintiff did not directly purchase the product.” Def.’s Br. at 28. The Court will address each state’s unjust enrichment laws in turn.

In Texas, Georgia, Tennessee, and Alabama, unjust enrichment actions may not succeed in the face of a governing contract, such as an express warranty. *In re Atlas Roofing Corp. Chalet Shingle Products Liab. Litig.*, No. 1:13-CV-2195-TWT, 2014 WL 3360233, at *3 (N.D.Ga. July 9, 2014) (“Under Georgia law, ‘unjust enrichment is available only when there is no legal contract.’ ”) (quoting *American Casual Dining, L.P. v. Moe’s Sw. Grill, L.L.C.*, 426 F.Supp.2d 1356, 1372 (N.D.Ga.2006));¹² *Johnson v. Wells Fargo Bank, NA*, 999 F.Supp.2d 919, 929 (N.D.Tex.2014) (“Because a claim for unjust enrichment is “based on quasi-contract,” it is “unavailable when a valid, express contract governing the subject matter of the dispute exists.”); *Branch Banking & Trust Co. v. Howard*, No. CIV.A. 12-0175-WS-N, 2013 WL 951652, at *5 (S.D.Ala. Mar.8, 2013) (“Alabama law is clear that quasi-contractual, equitable remedies such as unjust enrichment are not cognizable in the presence of an express contract between the parties that governs the same subject matter.”). Because the parties here do not dispute the existence of a governing express warranty, Count IX as asserted by McCoy, McMahon, the Medders, Boyd, and the Coles must be dismissed.

¹² Plaintiffs points to *Clark v. Aaron's, Inc.*, 914 F.Supp.2d 1301, 1309 (N.D.Ga.2012), for the proposition that an unjust enrichment claim may be pled in the alternative under Georgia law. *See also WESI, LLC v. Compass Envtl., Inc.*, 509 F.Supp.2d 1353, 1363 & n. 12 (N.D.Ga.2007). While case law on this issue appears to be mixed, the Georgia Court of Appeals has found that an unjust enrichment claim, pled as an alternative to recovery under a contract claim, fails as a matter of law if a governing contractual provision is indisputably in place. *Tidikis v. Network for Med. Commc'n & Research LLC*, 274 Ga.App. 807, 619 S.E.2d 481, 486 (Ga.Ct.App.2005); *see also Huddle House, Inc. v. Two Views, Inc.*, No. 1:12-CV-03239-RWS, 2013 WL 1390611, at *4 (N.D.Ga. Apr.4, 2013). Because the parties do not dispute the validity or the applicability of the express warranty at issue here, the Court finds that an unjust enrichment claim cannot survive the Rule 12(b)(6) analysis even if pled in the alternative.

Meanwhile, in New Jersey, Pennsylvania, and Alabama, it is necessary to assert a “sufficiently direct relationship” between the plaintiff and the defendant to recover on an unjust enrichment claim. *Snyder v. Farnam Companies, Inc.*,

792 F.Supp.2d 712, 724 (D.N.J.2011) (“Since Plaintiffs have failed to allege that they purchased the Products directly from Defendants, they cannot rightfully expect any remuneration from Defendants, since they never directly conferred a benefit on Defendants.”); *Schmidt v. Ford Motor Co.*, 972 F.Supp.2d 712, 721 (E.D.Pa.2013) (“The ‘benefit’ must be conferred by the plaintiff directly-indirect benefits bestowed by third parties will not support a claim for unjust enrichment.”); *Danny Lynn Elec. & Plumbing, LLC v. Veolia ES Solid Waste Se., Inc.*, No. 2:09CV192-MHT, 2011 WL 2893629, at *6 (M.D.Ala. July 19, 2011) (“[T]he plaintiffs’ unjust-enrichment claim should be dismissed as to the individual defendants because the plaintiffs did not confer a direct benefit on those individuals. In Alabama, ‘the essence of unjust enrichment is that a plaintiff can prove facts showing that defendant holds money which, in equity and good conscience, belongs to plaintiff or holds money which was improperly paid to defendant because of mistake or fraud.’ ” (quoting *Hancock-Hazlett General Const. Co., Inc. v. Trane Co.*, 499 So.2d 1385, 1387 (Ala.1986))). Here, a direct relationship between Plaintiffs and Defendants do not exist, because Plaintiffs did not directly purchase the PEX Products from Defendant. Therefore, Count IX, as asserted by Monica and the Pepernos,¹³ must be dismissed.

¹³ The Court already *supra* dismissed Boyd's unjust enrichment claim under Alabama law, on the basis of the existence of a governing express contract.

^{*15} Because each Plaintiffs state law bars a claim for unjust enrichment under the circumstances, Count IX is dismissed in its entirety.

g. Count X—Declaratory and Injunctive Relief

Finally, in Count X, Plaintiffs include a claim for “declaratory and injunctive relief.” FAC ¶¶ 213–214. However, declaratory relief and injunctive relief, as their names imply, are remedies, not causes of action. Accordingly, the Court dismisses Count X. *See Chruby v. Kowaleski*, 534 Fed. App'x 156, 160 n. 2 (3d Cir.2013) (affirming dismissal of a claim that was solely for a remedy).

V. CONCLUSION

For the foregoing reasons, Defendants' Partial Motion to Dismiss is GRANTED IN PART. Counts II, III, and IV are dismissed as asserted by Monica, and Counts I, II, III, and IV are dismissed as asserted by the Coles; both sets of plaintiffs are granted leave to file claims under the NJPLA

and the TPLA, respectively. Count I is dismissed without prejudice as asserted by McCoy. Counts I and II are dismissed without prejudice as asserted by McMahon. As asserted by all Plaintiffs, Counts III, IV, VI, VII, and VIII are dismissed without prejudice, and Counts V, IX, and X are dismissed. Count II as asserted by McCoy, however, may proceed.

An appropriate order shall follow.

All Citations

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TAB 11

2019 WL 1370414

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Ruth Ann COOPER, D.P.M., individually
and as the representative of a class of
similarly-situated persons, Plaintiff,
v.

MEDIMETRIKS PHARMACEUTICALS,
INC., Defendant.

Civil Action No. 18-11987 (JLL)

Signed 03/25/2019

Attorneys and Law Firms

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Defendant.

OPINION

JOSE L. LINARES, Chief Judge

*1 The plaintiff, Ruth Ann Cooper, D.P.M., brings this putative class action on behalf of herself and all others who are similarly situated against the defendant, Medimetriks Pharmaceuticals, Inc. (hereinafter, "Medimetriks"). (ECF No. 8.) Cooper asserts the following claims for:

- violations of the Junk Fax Prevention Act (hereinafter, "the JFPA"), 47 U.S.C. § 227, concerning faxes that were sent by Medimetriks that failed to provide a notice to recipients of the right to opt out of receiving such faxes and a manner in which to do so, and that were received by those who: (a) had not expressly provided permission to Medimetriks to send such faxes (hereinafter, "the Unsolicited JFPA Claims"), and (b) had expressly provided permission to Medimetriks to send such faxes (hereinafter, "the Solicited JFPA Claims");
- violations of the New Jersey Junk Fax Act (hereinafter, "the NJJFA"), N.J.S.A. 56:8-157, *et seq.*;

- violations of the New Jersey Consumer Fraud Act (hereinafter, "the NJCFA"); and
- attorney fees related to each of the aforementioned claims.

For the sake of clarity, the Court notes here that the JFPA sets forth opt-out notice requirements. *See* 47 U.S.C. § 227(b)(1)–(2). Among other things, the JFPA requires faxed advertisements to contain a notice on the first page that clearly and conspicuously advises that a recipient is legally entitled to opt out from any future faxed advertisements from the sender, and to provide a means to make an opt-out request to that sender. *Id.* Furthermore, the JFPA provides for a private cause of action. *See* 47 U.S.C. § 227(b)(3).

Currently pending before the Court is the motion by Medimetriks pursuant to **Federal Rule of Civil Procedure** (hereinafter, "Rule") 12(b)(6) to dismiss the entire amended complaint. (ECF No. 13 through ECF No. 13-3; ECF No. 19.) In response, Cooper voluntarily withdraws the claims that were brought under the NJCFA, but she otherwise opposes the motion. (ECF No. 18 at 24 (Cooper's withdrawal of the NJCFA claims); *id.* at 8–25 (Cooper's arguments in opposition).)

The Court resolves the motion upon a review of the papers and without oral argument. *See* L. Civ. R. 78.1(b). For the following reasons, the motion is: (1) granted to the extent that it addresses the Solicited JFPA Claims, the NJJFA Claims, and the claims for attorney fees that are related to the Solicited JFPA Claims and the NJJFA Claims; (2) administratively terminated to the extent that it addresses claims brought under the NJCFA and the claims for attorney fees that are related thereto, because the NJCFA claims have been withdrawn; and (3) denied to the extent that it addresses the Unsolicited JFPA Claims and the claims for attorney fees that are related thereto.

I. BACKGROUND

Cooper is a podiatrist who practices in Cincinnati, Ohio. (ECF No. 8 at 3 (the amended complaint alleging that Cooper is a citizen of Ohio); *see also* ECF No. 8-1 at 2–8 (faxes sent by Medimetriks to Cooper that list her office as being located in Cincinnati, Ohio).) Cooper alleges that Medimetriks is a pharmaceutical company that is located in Fairfield, New Jersey, and that specializes in podiatry and dermatology medications. (ECF No. 8 at 3–4.) Cooper further alleges that Medimetriks "sent facsimile transmissions of unsolicited

advertisements ... describ[ing] the commercial availability or quality of [its] products, goods and services" to her office on seven separate occasions between May 2016 and July 2018 "without the required opt-out language." (*Id.* at 1–2, 4.)

*2 The faxes contained offers made directly to Cooper for free samples of prescription medications sold by Medimetriks for Cooper to provide to patients. (*Id.* at 4.) The first two faxes that Cooper received from Medimetriks were in the following format:

From: 9732273890 Page 1/1 Date: 5/8/2016 12:56:18 AM
 5/8/2016 12:55 AM FROM: Medimetriks Pharm. To: 15139436115 Page: 001 of 001



SAMPLE REQUEST FORM



with REHYLA® HAIR+BODY CLEANSER

Up to 3 tubes

Doctor: Ruth Cooper, DPM	Specialty: Podiatry
Address: 4415-B Alcholtz Road	Suite/Floor: Suite 200
City: Cincinnati	State: OH Zip: 45245
Phone: 513-943-0400	Fax: 513-943-6115
State License #: 36.002540	Contact (optional):
Email (optional):	

In compliance with the Prescription Drug Marketing Act (PMDA) regulations, please complete and verify all the information listed above. Incomplete requests cannot be processed. Please sign and date this form indicating your request for these samples and fax it to Medimetriks Pharmaceuticals, Inc. (973) 882-7502.

I certify that I am a licensed practitioner who can legally prescribe in my state. I am requesting product samples so that I may have the opportunity to evaluate the tolerability and effectiveness on appropriate patients. I will not sell, offer to sell, trade or barter samples, nor will I seek reimbursement from any payer for providing these samples to a patient. I further certify this is my personal, original signature.

Physician Signature: _____ Date: _____

Request Date: 5/8/2016 Request Expires: 6/4/2016

Keep your original, signed hard copy form in your office files to comply with federal law.

PLEASE RETURN VIA FAX TO:
 Medimetriks Pharmaceuticals, Inc. (973) 882-7502

20160502CCFAX176327

If you have questions or concerns regarding any Medimetriks Pharmaceuticals brand, please call Medimetriks Customer Service at (973) 882-7512, ext. 234, Monday through Friday from 9 am to 5 pm ET.

303 Route 46 West • Fairfield, New Jersey 07006-2402 • Ph: (973) 882-7512 • Fax: (973) 882-7502 • www.medimetriks.com
 This fax was received by GFI FaxMaker fax server. For more information, visit: http://www.gfi.com

(ECF No. 8-1 at 2.) The next five faxes that Cooper received were in this format:

From: 9732273890 Page: 1/1 Date: 7/30/2016 8:09:27 PM
 7/30/2016 8:09:21 FROM: Medimetriks Pharm. To: 3139436115 Page: 001 of 001



SAMPLE REQUEST FORM



Up to 6 bins of 6 samples each

Doctor: Ruth Cooper, DPM	Specialty: Podiatry
Address: 4415-B Alcholtz Road	Suite/Floor: Suite 200
City: Cincinnati	State: OH Zip: 45245
Phone: 513-943-0400	Fax: 513-943-6115
State License #: 36.002540	Contact (optional):
Email (optional):	

In compliance with the Prescription Drug Marketing Act (PMDA) regulations, please complete and verify all the information listed above. Incomplete requests cannot be processed. Please sign and date this form indicating your request for these samples and fax it to Medimetriks Pharmaceuticals, Inc. (973) 882-7502.

I certify that I am a licensed practitioner who can legally prescribe in my state. I am requesting product samples so that I may have the opportunity to evaluate the tolerability and effectiveness on appropriate patients. I will not sell, offer to sell, trade or barter samples, nor will I seek reimbursement from any payer for providing these samples to a patient. I further certify this is my personal, original signature.

Physician Signature: _____ Date: _____

Request Date: 7/30/2016 Request Expires: 8/29/2016

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 PLEASE RETURN VIA FAX TO:
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 POD20180730LCBC176327

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303 Route 46 West • Fairfield, New Jersey 07006-2402 • Ph: (973) 882-7512 • Fax: (973) 882-7502 • www.medimetriks.com
 This fax was received by GFI FaxMaker fax server. For more information, visit: http://www.gfi.com

(*Id.* at 8.)

Cooper alleges that neither she nor anyone on her behalf gave permission to Medimetriks to send her these faxes. (ECF No. 8 at 4.) Furthermore, Cooper alleges that these faxes constituted advertisements under the provisions of the JFPA and the NJJFA. (*Id.*) In addition, Cooper alleges that the faxes lacked the notice that is required pursuant to the JFPA and NJJFA informing her of the opportunity to opt out of receiving any further faxed advertisements from Medimetriks and providing a manner in which to opt out. (*Id.* at 12.) Cooper now purports to bring claims on behalf of those who received both solicited and unsolicited faxes from Medimetriks where said faxes lacked the opt-out notice.

II. DISCUSSION

A. Rule 12(b)(6) Standard

It is not necessary for this Court to restate the standard for resolving this motion to dismiss the amended complaint that has been made pursuant to Rule 12(b)(6), because that standard has already been enunciated. See *Palakovic v. Wetzel*, 854 F.3d 209, 219–20 (3d Cir. 2017) (setting forth the standard, and explaining the holdings in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009)); see also *Fowler v. UPMC Shadyside*, 578 F.3d

2019 WL 1370414

203, 209–12 (3d Cir. 2009) (setting forth the standard, and explaining the holdings in *Iqbal* and *Twombly*).

B. Solicited JFPA Claims and Related Claims For Attorney Fees

Cooper alleges that she did not: (1) give permission to Medimetriks to fax advertisements to her; or (2) solicit such faxed advertisements in any way. (ECF No. 8.) Cooper emphasizes these allegations in opposition to the motion to dismiss. (See ECF No. 18 at 17 (alleging that “Medimetriks repeatedly sent unsolicited facsimiles to Dr. Cooper offering her free samples of Medimetriks’ products”); *id.* at 22 (arguing that “[f]rom a factual standpoint, Dr. Cooper alleged the faxes she received from Medimetriks were unsolicited; *i.e.*, ‘without [her] prior express invitation or permission’ ”).)

As a result, Cooper is unable to proceed as a class representative for those who might have standing to bring the Solicited JFPA Claims, because Cooper is not—in contrast to the caption of the amended complaint—a “similarly-situated person[]” insofar as these particular claims are concerned. (ECF No. 8 at 1.) As correctly argued by Medimetriks, Cooper is unable to represent the interests of the recipients who either solicited or gave permission to Medimetriks to send them faxes, but who then received said faxes without the opt-out information, as Cooper’s alleged experiences as to the faxes from Medimetriks were different. (See ECF No. 13-1 at 22–23 (Medimetriks arguing same).) It is well-settled law in the class action context that “[r]epresentatives must be part of the class and possess the *same* interest and suffer the *same* injury as the class members.” *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 594–95 (1997) (emphasis added); *see also Zimmerman v. HBO Affiliate Grp.*, 834 F.2d 1163, 1169–70 (3d Cir. 1987) (affirming the dismissal of a cause of action due to the named plaintiff’s failure to state a claim, because “to be a class representative on a particular claim, the plaintiff must himself have a cause of action on that claim”).

*3 Furthermore, a named plaintiff in a purported class action cannot conjure up standing by “alleg[ing] a bare procedural violation, divorced from any concrete harm” to him or her, even where “a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right,” unless that plaintiff has alleged an injury-in-fact that is “fairly traceable to the challenged conduct of the defendant.”

Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547, 1549 (2016). Even though—as with the situation in the instant case—“a suit may be a class action … [it] adds nothing to the question of standing, for even named plaintiffs who represent

a class must allege and show that they personally have been injured, not that [an] injury has been suffered by other, unidentified members of the class to which they belong.” *Id.* at 1547 n.6 (citations and internal quotes omitted); *see also Ehrheart v. Verizon Wireless*, 609 F.3d 590, 607 (3d Cir. 2010) (holding the same). The Court cannot allow Cooper to proceed as a representative on behalf of those covered by the Solicited JFPA Claims, as Cooper herself neither solicited nor gave permission to receive the faxes from Medimetriks. *See Frank v. Gaos*, No. 17-961, 2019 WL 1264582, at *3 (U.S. Mar. 20, 2019) (remanding a class action case for further proceedings, because the lower courts failed to determine whether the named plaintiffs had personally experienced the alleged violation at issue, and thus whether those plaintiffs had standing to bring those particular claims).

Therefore, the Solicited JFPA Claims and the claims for attorney fees that are related to the Solicited JFPA Claims are dismissed. However, those claims are dismissed without prejudice, and with leave to Cooper to move for joinder of an additional plaintiff who indeed provided such permission to Medimetriks and then received faxes lacking the required opt-out information pursuant to the JFPA. By granting such leave, the Court is offering no opinion as to whether the Solicited JFPA Claims would then be found to be plausible or meritorious.

C. Unsolicited JFPA Claims and Related Claims For Attorney Fees

Cooper alleges that she did not permit Medimetriks to send her the faxes, and that the faxes did not contain opt-out information. Thus, the Court finds that Cooper has standing to proceed with the Solicited JFPA Claims. *See Amchem Prods., Inc.*, 521 U.S. at 594–95.

Medimetriks does not deny that the faxes fail to set forth any opt-out language. However, Medimetriks argues that Cooper has not plausibly alleged that the faxes at issue were advertisements, and argues that the faxes offer nothing for sale and were sent to Cooper in her capacity as a podiatrist in order to assist her with patient care. (ECF No. 13-1 at 8, 12.) Medimetriks further argues that “the faxes did not propose any commercial transaction with” Cooper, and thus argues that the JFPA does not apply here. (*Id.* at 8.)

The JFPA defines an “unsolicited advertisement” as “any material advertising the commercial availability or quality of any property, goods, or services which is transmitted to any person without that person’s prior express invitation or

permission, in writing or otherwise.” 47 U.S.C. § 227(a)(5); *see also* 47 U.S.C. 227(b)(1) (providing that “[i]t shall be unlawful for any person ... to send, to a telephone facsimile machine, an unsolicited advertisement”). Thus, a fax can still set forth a commercial pretext that falls under the regulation of the JFPA if it is “an indirect commercial solicitation, or pretext for a commercial solicitation.” *Sandusky Wellness Ctr., LLC v. Medco Health Sols., Inc.*, 788 F.3d 218, 225 (6th Cir. 2015). All that is required for an unsolicited fax to merit scrutiny under the JFPA is for that fax to “draw[] the relevant market’s attention to its product to promote its sale (albeit indirectly).” *Id.* at 222; *see also* *Physicians Healthsource, Inc. v. Janssen Pharms., Inc.*, No. 12-2132, 2013 WL 486207, at *6 (D.N.J. Feb. 6, 2013) (holding insofar as the JFPA is concerned that “publications may be part of an overall marketing campaign to promote the commercial availability and quality of a sender’s goods or services,” and thus “while the message is informational to the extent that it is notifying the recipient of free ... services, the message can also be construed as [an] advertisement because it contains statements promoting the availability and quality of certain goods or services”). Indeed, as another Federal District Court has held in denying a motion to dismiss by a pharmaceutical-company defendant in a similar case that concerned claims brought under the JFPA, it is certainly plausible in this case that Medimetriks sent the unsolicited faxes to Cooper in her capacity as a podiatrist as advertisements to “promote[] the sale of its products to [her] patients, albeit indirectly, by passing on free samples through [her],” and that “the offer of free products is a vehicle to advertise [the defendant’s] products and sell those products to [her] patients.” *Cooper v. NeilMed Pharms., Inc.*, No. 16-945, 2017 WL 4349085, at *4 (S.D. Ohio Sept. 29, 2017).

*4 As a result, the Unsolicited JFPA Claims will be permitted to go forward, because the Court finds that the faxes at issue may plausibly be considered to be unsolicited advertisements at this juncture. In addition, the claims for attorney fees that are related to the Unsolicited JFPA Claims will also proceed at this juncture, as the Court is utilizing the discretion to refrain from determining the merits of the claims for attorney fees until the Unsolicited JFPA Claims themselves have been resolved on the merits. *See Artemi Ltd. v. Safe-Strap Co., Inc.*, No. 03-3382, 2013 WL 6860734, at *6 n.7 (D.N.J. Dec. 30, 2013) (denying without prejudice a motion to dismiss claims for attorney fees where the underlying claims in a patent infringement case remained viable, because “decisions concerning entitlement

to attorney[] fees can abide the resolution of the merits of th[e] suit”).

D. NJJFA Claims

Medimetriks argues that Cooper may not proceed in this litigation as the class representative for the claims brought under the NJJFA because she received the faxes in Ohio, and because the NJJFA pertains only to the recipients of fax advertisements within New Jersey. (ECF No. 13-1 at 9.) The NJJFA protects New Jersey residents from being forced to receive unsolicited fax advertisements without being provided with an option to opt out of receiving such faxes. N.J.S.A. 56:8-157; N.J.S.A. 56:8-158(b). Specifically, the NJJFA provides that “[a] person within this State shall not ... send an unsolicited advertisement to a telephone facsimile machine *within this State*.” N.J.S.A. 56:8-158(a).

As discussed earlier by the Court as to the Solicited JFPA Claims, it is well-settled law in the class action context that “[r]epresentatives must be part of the class and possess the same interest and suffer the same injury as the class members.” *Amchem Prods., Inc.*, 521 U.S. at 594–95. Cooper is the only named plaintiff in this Action. Cooper is not a New Jersey resident (she is a resident of Ohio) and Cooper did not suffer any alleged injuries in New Jersey (she was allegedly injured in Ohio), and thus Cooper is barred from proceeding as a class representative for the NJJFA claims. *See McGuire v. BMW of N. Am., LLC*, No. 13-7356, 2014 WL 2566132, at *6 (D.N.J. June 6, 2014) (in addressing a motion to dismiss putative class action claims, holding that the plaintiff lacked standing to assert claims under the laws of the states in which he did not reside or in which he suffered no injury, because the named plaintiff in a proposed class action should not be permitted to engage in lengthy class discovery for injuries in relation to every state in the country). In fact, Cooper concedes that she does not possess an individual claim under the NJJFA in this action, and that she is uncertain whether anyone in New Jersey even received the subject faxes from Medimetriks. (ECF No. 18 at 23 (Cooper stating that her “faxes were not received in New Jersey,” and that she “is seeking to represent all persons who received the ... Faxes — some of whom *likely* received these faxes in New Jersey and *may* ... be entitled to additional remedies under New Jersey law”)(emphasis added).)

Therefore, the NJJFA Claims and the claims for attorney fees that are related to the NJJFA Claims are dismissed. However, those claims are dismissed without prejudice, and with leave to Cooper to move for joinder of an additional plaintiff who

was allegedly injured by receiving faxes from Medimetriks in violation of the NJJFA within New Jersey.

E. Argument Raised By Medimetriks In The Reply Brief

Medimetriks suggests in its reply brief that the Court might consider staying this case at this juncture. (ECF No. 19 at 15–16.) Medimetriks argues that the Court may await the resolution of a matter that is pending in the United States Supreme Court concerning the holding in *Carlton & Harris Chiropractic, Inc. v. PDR Network, LLC*, 883 F.3d 459, 466 (4th Cir. 2018), in which a divided panel of the Fourth Circuit Court of Appeals held that a separate federal statute, *i.e.*, the Hobbs Act, precluded the District Court from considering whether an offer for a free e-book constituted an advertisement under the JFPA. See *PDR Network, LLC v. Carlton & Harris Chiropractic, Inc.*, 139 S. Ct. 478 (2018) (granting a petition for a writ of certiorari).

*5 However, the Court will not rule upon an argument that has been raised in the first instance in a reply brief. See *Alston v. Forsyth*, 379 F. App'x 126, 129 (3d Cir. 2010) (vacating an order granting summary judgment wherein the District Court accepted an argument that was raised for the first time in a reply brief as being dispositive of claims, because there was

no meaningful opportunity to present arguments or evidence in opposition to the decisive issue); *see also Reap v. Cont'l Cas. Co.*, 199 F.R.D. 536, 550 n.10 (D.N.J. 2001) (holding that it is improper to raise arguments for the first time in reply papers). If Medimetriks desired the Court to hold this case in abeyance, then it should have sought to do so by a properly-noticed motion that permitted Cooper to either oppose or join in that request.

III. CONCLUSION

For the aforementioned reasons: (1) the Solicited JFPA Claims, the NJJFA Claims, and the claims for attorney fees that are related to the Solicited JFPA Claims and the NJJFA Claims are dismissed; (2) the NJCFA claims and the claims for attorney fees that are related thereto are deemed to be withdrawn; and (3) the Unsolicited JFPA Claims and the claims for attorney fees that are related thereto remain viable. An appropriate Order follows this Opinion.

All Citations

Slip Copy, 2019 WL 1370414

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TAB 12

 KeyCite Yellow Flag - Negative Treatment
On Reconsideration in Part [Crouch v. Johnson & Johnson Consumer Companies, Inc.](#), D.N.J., August 2, 2010

2010 WL 1530152

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Jennifer CROUCH, individually and on behalf of all others similarly situated, Plaintiffs,

v.

JOHNSON & JOHNSON CONSUMER COMPANIES, INC.; Kimberly Clark Corporation; Wal-Mart Stores, Inc.; and John Doe, Defendants.

Civil Action No. 09-CV-2905 (DMC).

April 15, 2010.

West KeySummary

1 **Antitrust and Trade**

Regulation  Exclusive and Concurrent Remedies or Laws

Products Liability  Economic losses; damage to product itself

Products Liability  Cosmetics, soaps, and hair-care products

Products Liability  Nature and form of remedy

A mother failed to state a New Jersey law consumer fraud claim against a baby shampoo manufacturer. The mother's claims were preempted by the New Jersey Product Liability Act, which barred claims based on pure economic loss. The mother alleged that she suffered an economic loss at the time of her shampoo purchase because the shampoo contained undisclosed toxins and an ingredient banned by the FDA. N.J.S.A. 2A:58C-1b(2).

[8 Cases that cite this headnote](#)

Attorneys and Law Firms

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OPINION

[DENNIS M. CAVANAUGH](#), District Judge.

*1 This matter comes before the Court upon motion by Johnson & Johnson Consumer Companies, Inc. ("J & J"), Kimberly-Clark Corporation ("KC") and Wal-Mart Stores, Inc. ("Wal-Mart") (collectively, "Defendants") to dismiss the Amended Class Action Complaint ("Complaint") of Jennifer Crouch, individually and on behalf of all others similarly situated, ("Plaintiffs") for failure to state a claim pursuant to [Fed.R.Civ.P. 12\(b\)\(6\)](#) and for lack of subject matter jurisdiction pursuant to Fed. R. Civ. 12(b)(1). Pursuant to [Fed.R.Civ.P. 78](#), no oral argument was heard. After considering the submissions of all parties, it is the decision of this Court for the reasons herein expressed that Defendants' motion to dismiss is **granted in part** and **denied in part**.

I BACKGROUND

The Complaint is brought individually and on behalf of all class purchasers ("Class Members") of J & J's Baby Shampoo, J & J's Moisture Care Baby Wash, Aveeno Baby Soothing Relief Creamy Wash, Equate Tearless Baby Wash and Huggies Soft Skin Shea Butter Baby Wipes ("products"). Plaintiffs allege that "although Defendants represented that the products they marketed, distributed, promoted, sold, and/or made were safe for children, the Children's Personal Care Products were actually contaminated with toxic chemicals linked to increased [cancer](#) risk, adverse skin reactions, and other serious health problems." (Plaintiffs' Complaint ("Pl.Compl."), ¶ 1). Plaintiffs further allege that despite representations made by these companies that their products are safe and gentle, these products contain contaminants that are not disclosed on the label and that could otherwise have been removed pursuant to a process called vacuum stripping. (Pl.Compl., ¶¶ 2, 5).

2010 WL 1530152

Plaintiffs assert that independent lab tests, conducted in accordance with regulations promulgated by the Environmental Protection Agency (“EPA”), reveal that J & J’s Baby Shampoo contains methylene chloride in levels as high as 1.1 ppm, 1,4 dioxane levels as high as 38 ppm, and formaldehyde levels as high as 210 ppm. (Pl.Compl., ¶¶ 3, 46). “After testing, [J & J’s] Moisture Care Baby Wash was found to be contaminated with 1,4-dioxane. Independent Lab Tests found 1,4-dioxane levels of 22 ppm.” (Pl.Compl., ¶ 56). “After testing, [J & J’s] Aveeno Baby Soothing Relief Creamy Wash was found to be contaminated with 1,4-dioxane. Independent Lab Tests found 1,4-dioxane levels of 4.0 ppm.” (Pl.Compl., ¶ 66). Plaintiffs also assert that each of the foregoing qualifies as a cosmetic pursuant to the Food Drug and Cosmetic Act because each is “intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance” and is not “soap.” 21 U.S.C. § 321(i) (2008). (Pl.Compl., ¶¶ 50, 60, 69).

Plaintiffs also contend that “[a]fter testing, [] Kimberly Clark’s Huggies Soft Skin Shea Butter Baby Wipes were found to be contaminated with 1,4-dioxane. Independent Lab Tests found 1,4-dioxane levels of .53 ppm.” (Pl.Compl., ¶ 74). Moreover, Plaintiffs assert that this product qualifies as a cosmetic pursuant to the Food Drug and Cosmetic Act because it is “intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance” and is not “soap.” 21 U.S.C. § 321(I) (2008). (Pl.Compl., ¶ 77).

*2 Additionally, Plaintiffs allege that “[a]fter testing, [Wal-Mart’s] Equate Tearless Baby Wash was found to be contaminated with methylene chloride, 1,4-dioxane, and formaldehyde. Independent Lab Tests found methylene chloride levels of 0.57 ppm, 1,4-dioxane levels of 39 ppm, and formaldehyde levels of 350 ppm.” (Pl.Compl., ¶ 83). Plaintiffs assert that this product qualifies as a cosmetic pursuant to the Food Drug and Cosmetic Act because it is “intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance” and is not “soap.” 21 U.S.C. § 321(I) (2008). (Pl.Compl., ¶ 86).

Count I of the Complaint asserts a claim for breach of implied warranty pursuant to the Uniform Commercial Code

(“UCC”) § 2-314. (Pl. Compl. at 102). Count II of the Complaint asserts a claim for breach of implied warranties of merchantability and fitness for a particular use. (Pl.Compl., ¶ 114). Count III of the Complaint asserts a claim for unfair and deceptive trade practices. (Pl.Compl., ¶ 121). Count IV of the Complaint asserts a claim for unjust enrichment. (Pl.Compl., ¶ 129).

II. STANDARD OF REVIEW

“There is a fundamental difference of review under Rule 12(b)(1), where the existence of disputed facts will not preclude the court from evaluating the merits of the jurisdictional claim, and Rule 12(b)(6) where the court is required to accept as true all the allegations of the complaint and all inferences arising from them.” *Anjelino v. New York*, 200 F.3d 73, 87 (3d Cir.1999). “[T]he threshold to withstand a motion to dismiss under [Rule] 12(b)(1) is thus lower than that required to withstand a Rule 12(b)(6) motion.” *Kehr Packages Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir.1991)).

A. Fed.R.Civ.P. 12(b)(6)

“The [d]istrict [c]ourt, in deciding a motion under Fed.R.Civ.P. 12(b)(6), [is] required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff].” *Phillips v. County of Allegheny*, 515 F.3d 224, 228 (3d Cir.2008). “While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, [] a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). “[A court is] not bound to accept as true a legal conclusion couched as a factual allegation.” *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986). “Factual allegations must be enough to raise a right to relief above a speculative level, [] on the assumption that all factual allegations in the complaint are true (even if doubtful in fact).” *Bell*, 550 U.S. at 555–56.

B. Fed.R.Civ.P. 12(b)(1)

*3 “On a Rule 12(b)(1) motion, no presumption of truthfulness attaches to the allegations of the plaintiff.” *CNA v. United States*, 535 F.3d 132, 139 (3d Cir.2008). A facial attack “concerns ‘an alleged pleading deficiency’ whereas a factual attack concerns the actual failure of [a plaintiff’s] claims to

2010 WL 1530152

comport [factually] with the jurisdictional prerequisites.” *Id.* (citing *U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir.2007)).

III. DISCUSSION

A. Standing

To bring a suit in a federal court, Plaintiffs must have standing pursuant to Article III of the United States Constitution. To establish standing under Article III, Plaintiffs must show: (1) injury in fact; (2) causation; and (3) redressability. *Horvath v. Keystone Health Plan E, Inc.*, 333 F.3d 450, 455 (3d Cir.2003); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992).

First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Id. (citing *AT & T Communications of N.J., Inc. v. Verizon N.J., Inc.*, 270 F.3d 162, 170 (3d Cir.2001)). “The injury must affect the plaintiff in a personal and individual way.” *Pitt News v. Fisher*, 215 F.3d 354 (3d Cir.2000); *Alston v. Countrywide Fin. Corp.*, 585 F.3d 753, 763 (3d Cir.2009).

“[O]rdinarily, one may not claim standing to vindicate the constitutional rights of some third party.” *Pitt*, 215 at 362. “We apply this prudential rule against third party standing even when the requirements of Article III have been met, to ‘avoid deciding questions of broad social import ... [and] to limit access to the federal courts to those litigants best suited to assert a particular claim.’ “ *Id.* (citing *Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 99–100, 99 S.Ct.

1601, 60 L.Ed.2d 66 (1979)). “[W]hen the asserted harm is a ‘generalized grievance’ shared in substantially equal measure by all or a large class of citizens, that harm alone normally does not warrant exercise of jurisdiction.” *Berg v. Obama*, 586 F.3d 234, 239 (2009) (citing *Warth v. Seldin*, 422 U.S. 490, 499, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975)). Furthermore, “[t]he standing inquiry does not change in the context of a putative class action.... [S]tanding cannot be predicated on an injury which the plaintiff has not suffered, nor can it be acquired through the back door of a class action.” *Koronthaly v. L’Oreal*, 2008 U.S. Dist. LEXIS 59024, *12 (D.N.J. July 25, 2008).

*4 Defendants contend that “Plaintiff[s]’ failure to plead any manifest, present, non-speculative injury, and failure to allege that [the products] did not provide cleansing benefits” requires the Court to conclude that Plaintiffs lack standing in the instant matter. In reliance upon this Court’s decision in *Koronthaly*, Defendants assert that Plaintiffs’ demand for a refund of the purchase price as a consequence of exposure to Defendants’ products fails to establish an injury-in-fact and therefore, is not sufficient to confer standing where the alleged harm is no more than conjectural or hypothetical. As a result, Defendants claim that the absence of a cognizable injury and thereby standing in this matter requires dismissal pursuant to Fed.R.Civ.P. 12(b)(1).

In response, Plaintiffs contend that economic injury is sufficient to confer standing in this matter, relying upon *Clinton v. City of New York*, 524 U.S. 417, 118 S.Ct. 2091, 141 L.Ed.2d 393 (1998) and *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286 (3d Cir.2005). Plaintiffs contend that where the product contains undisclosed toxins and an ingredient banned by the FDA, the injury arises at the time of purchase. In distinguishing the *Koronthaly v. L’Oreal* case, citing to this Court’s disposition on a motion for reconsideration, Plaintiffs assert that unlike *Koronthaly* where this Court determined that plaintiff “provided no authoritative evidence that the lead levels in defendants’ lipstick products constitute[d] a dangerous amount or [were] in some way prohibited[,]” the present action involves methylene chloride, a substance banned by the FDA for use in cosmetics. 2008 U.S. Dist. LEXIS 86419, *11, 2008 WL 4723862 (D.N.J. Oct. 24, 2008). Further, Plaintiffs contend that the EPA classifies the other chemicals at issue as probable carcinogens. Lastly, Plaintiffs assert that their claims should stand because Plaintiffs have at least raised an issue of fact with respect to whether the chemicals contained in Defendants’ products are dangerous in amount.

The *Koronthaly* case involved the purchase of a lipstick containing lead, the content of which was not subject to FDA regulation. *Id.* at *2–3. However, the lead content of the lipstick appeared dangerous when compared to the lead content regulation imposed by the FDA on candy. *Id.* In the absence of an FDA regulation concerning lead content in lipstick, or other legal prohibition, the plaintiff could not “seek a remedy for a harm that she ha[d] not actually or allegedly suffered.” Moreover, this Court accorded great weight to the decision in *Williams v. Purdue Pharma Co.*, 297 F.Supp.2d 171 (D.D.C.2003), concluding that the “plaintiffs’ allegation of an economic injury in a products liability action was insufficient to establish injury-in-fact” because “without alleging that a product failed to perform as advertised, a plaintiff has received the benefit of his bargain and has no basis to recover purchase costs.” *Id.* at *13–14. Therefore, the *Williams* Court “remarked that benefit of the bargain injury could not sustain a claim of injury in fact.” *Id.*

*5 While the Court agrees that the assertion of an economic injury is not an automatic bar to standing, *Koronthaly* demonstrates that an exception has been recognized in the context of claims concerning defective products, absent a specific legal prohibition precluding particular ingredients or usages. Insofar as Plaintiffs’ claims pertain to allegedly toxic chemicals that have not been banned by the FDA for use in cosmetics, including 1,4-dioxane and formaldehyde, in accordance with *Koronthaly*, this Court concludes that any potential injury is too remote, hypothetical and/or conjectural to establish standing in this matter. However, insofar as Plaintiffs’ claims pertain to methylene chloride, a chemical explicitly banned for use by the FDA in any cosmetic, this Court declines to dismiss Plaintiffs’ claims pursuant to Fed.R.Civ.P. 12(b)(1) for lack of standing. At this stage, Plaintiffs are permitted to proceed only with respect to claims concerning J & J’s Baby Shampoo and Wal-Mart’s Equate Tearless Baby Wash. With respect to the other allegedly defective products and their manufacturers, Plaintiffs’ claims are dismissed.

B. Choice of Law

As a federal district court sitting in diversity, this Court must apply the choice of law rules of New Jersey, the forum state. See *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496–97, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941). New Jersey’s choice of law rules mandate that the determinative law is that of the state with the greatest interest in governing the particular issue. The first step is to determine whether a conflict

exists between the law of interested states, and then any conflict shall be determined on an issue-by-issue basis. “Under general conflict of laws principles, where the laws of the two jurisdictions would produce the same result on the particular issue presented, there is a ‘false conflict,’ and the court should avoid the choice-of-law question.” *Williams v. Stone*, 109 F.3d 890, 894 (3d Cir.1997). If there is a conflict, then the court must identify the governmental policies underlying the law of each state and how those policies are affected by each state’s contacts to the litigation. If the state’s law is not related to its contacts with the litigation, then the state does not have an interest in having its law applied to the underlying issue. See *Vezey v. Doremus*, 103 N.J. 244, 510 A.2d 1187, 1189 (N.J.1986). That is, if there is an actual conflict between the two states’ laws, the court then determines “which state has the most meaningful connections with and interests in the transaction and the parties.” *Spence-Parker v. Del. Riv. & Bay Authority*, 2009 U.S. Dist. LEXIS 75187, *20, 2009 WL 2602094 (D.N.J. Aug. 21, 2009). Where no actual conflict of law exists, no choice of law need be made. See *Zavala v. Wal-Mart Stores, Inc.*, 393 F.Supp.2d 295, 333 (D.N.J.2005). “If there is no actual conflict, the court must apply the law of New Jersey.” *LNT Merck Co. v. Dyson, Inc.*, 2009 U.S. Dist. LEXIS 62308, *6 (D.N.J. July 21, 2009) (citing *Lebegern v. Forman*, 471 F.3d 424, 428 (3d Cir.2006)). In that instance, a motion to dismiss under Fed.R.Civ.P. 12(b) (6) should be decided under New Jersey law. See *Gallerstein v. Berkshire Life Ins. Co. of America*, 2006 U.S. Dist. LEXIS 64487, *3, 2006 WL 2594862 (D.N.J. Sept. 11, 2006).

*6 The parties’ moving papers recognize that the outcome is the same regardless of whether New Jersey State Law or Kentucky State Law is applied to this diversity action. Therefore, the parties assert that no conflict of laws issue is present in the instant matter.

1. New Jersey State Law Breach of Warranty, Consumer Fraud and Unjust Enrichment Claims

Defendants assert that dismissal is required with respect to all Plaintiffs’ claims because the claims are based on alleged harm caused by a product and as a consequence, are subsumed by the New Jersey Product Liability Act (“PLA”). Plaintiffs argue that the PLA does not subsume Plaintiffs’ UCC or consumer protection claims because Plaintiffs neither assert themselves as “claimants” nor allege present or future physical injuries as a consequence of Defendants’ products. Plaintiffs further allege that the heart of the present matter is the economic harm caused by Defendants’ misrepresentations, omissions and breaches of

2010 WL 1530152

warranty. Additionally, Plaintiffs contend that the instant matter does not present a risk of double recovery, and that the claims asserted do not constitute a failure to warn cause of action pursuant to the PLA.

The New Jersey Supreme Court decision in *Sinclair v. Merck & Co.* is instructive. In *Sinclair v. Merck & Co.*, the Plaintiffs “alleged that as a result of their direct and prolonged consumption of *Vioxx*, they are at enhanced risk of serious undiagnosed and unrecognized *myocardial infarction*, commonly referred to as ‘silent heart attack,’ and other latent and unrecognized injuries.” 195 N.J. 51, 55, 948 A.2d 587 (2008). In that case, the plaintiffs asserted claims for negligence, violation of the Product Liability Act, violation of the Consumer Fraud Act, breach of express and implied warranties and unjust enrichment. *Id.* In dismissing the complaint in its entirety, New Jersey Supreme Court determined the following,

[p]laintiffs seek to avoid the requirements of the PLA by asserting their claims as CFA claims. However, the Legislature expressly provided in the PLA that claims for “harm caused by a product” are governed by the PLA “irrespective of the theory underlying the claim.” N.J.S.A. 2A:58C-1b(3). We explained in *Lead Paint*, *supra*, that “[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action in relating to harms caused by consumer and other products.” 191 N.J. at 436–37, 924 A.2d 484. As a result, we declared that “[i]n light of the clear intention of our Legislature to include all [product liability] claims within the scope of the PLA, we find no ground on which to conclude that the claims being raised by plaintiffs, regarding an ordinary household product used by consumers, were excluded from the scope of” the PLA. We reach the same conclusion here.

The language of the PLA represents a clear legislative intent that, despite the broad reach we give to the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product. The heart of plaintiffs' case is the potential for harm caused by Merck's drug. It is obviously a product liability claim. Plaintiffs' CFA claim does not fall within an exception to the PLA, but rather clearly falls within its scope. Consequently, plaintiffs may not maintain a CFA claim.

*7 *Id.* ^{1 2}

1 Although this Court permitted the CFA claims to proceed in *Nafar v. Hollywood Tanning Sys., Inc.*, in that case, the Plaintiff's claims and basis for distinction of the CFA from the PLA was the purchase of services, rather than the purchase of a defective product. 2007 U.S. Dist. LEXIS 26312, *12–14 (D.N.J. Apr. 5, 2007). CFA claims rooted in services are clearly distinguishable from claims grounded in products. The present action does not involve a claim for defective services.

2 Further, *In re Ford Motor Co. E-350 Van Products*, 2008 U.S. Dist. LEXIS 73690, *48 n. 9 (D.N.J. Sept. 3, 2008), where the Court found the *Sinclair* case “inapposite” “because, by design, the PLA ‘except[s] actions for harm caused by breach of an express warranty[,]’ which plaintiffs expressly allege[d].” On the basis of an express warranty, the Court concluded that *Sinclair* decision “does not mandate dismissal of unjust enrichment and state consumer fraud claims where a party does not plead a PLA claim.” *Id.* (internal citations omitted). Plaintiffs do not assert a claim for breach of an express warranty in the present action.

Similarly, at the heart of this matter is the potential for harm caused by the defective products, J & J Baby Shampoo, J & J Moisture Care Baby Wash, Aveeno Baby Soothing Relief Creamy Wash, Kimberly-Clark's Soft Skin Shea Butter Baby Wipes and John Doe and Wal-Mart Equate Tearless Baby Wash, containing allegedly “toxic chemicals linked to increased *cancer* risk, adverse skin reactions, and other serious health problems.” (Compl., ¶ 2). Further, Plaintiffs allege that the products were rendered useless “because they were contaminated with dangerous and potentially cancer-causing chemicals and continued use of the products would require Plaintiffs and Class Members to knowingly continue and even increase the exposure of their vulnerable infants and children to the harmful contaminants.” (Compl., ¶ 2).

Consistent with the *Sinclair* decision, this Court concludes that the PLA subsumes all of Plaintiffs' claims, effectively precluding Plaintiffs' claims with respect to the CFA, and otherwise, in the absence of “harm” as defined by the PLA. The Court does not agree that articulating a claim in terms of pure economic harm where the core issue is the potential injury arising as a consequence of the products' allegedly harmful chemicals converts the underlying defective product claim into an independent and unrelated consumer fraud issue. Indeed, Plaintiffs' original Complaint contains a cause

2010 WL 1530152

of action for products liability strategically omitted from the amended Complaint. Limiting a claim to economic injury and the remedy sought to economic loss cannot be used to obviate the PLA.

The assertion of a claim pursuant to the PLA is premised upon a requisite level of harm, including:

- (a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.

N.J.S.A. 2A:58C-1b(2). Harm, for purposes of the PLA, does not include pure economic loss. Insofar as Plaintiffs concede that their injury is purely economic, Plaintiffs' claims cannot survive. Therefore, with respect to New Jersey law, in accordance with *Sinclair*, Plaintiffs' Complaint is dismissed without prejudice in its entirety.

2. Kentucky State Law Breach of Warranty, Consumer Fraud and Unjust Enrichment

Despite the parties' respective beliefs that there is no conflict of law issue present in the instant matter, it is not clear to the Court that product liability laws of Kentucky subsume related claims in the same manner as the New Jersey PLA. Therefore, upon dismissal of all New Jersey State Law claims and for purposes of inclusion, the Court will proceed by addressing the viability of Plaintiffs' claims under Kentucky State Law. If Plaintiffs have asserted viable claims pursuant to Kentucky State Law, then a conflict of law exists and the Court will undertake to ascertain which state has the superior interest in the litigation.

i. Consumer Fraud

*8 Defendants contend that Plaintiffs have no viable claims pursuant to Kentucky Consumer Protection Act ("CPA") because the Kentucky Products Liability Act ("KPLA") subsumes the CPA, because Plaintiffs fail to allege any non-speculative, ascertainable loss and finally, because Plaintiffs

fail to plead their claims with particularity in accordance with Fed.R.Civ.P. 9(b). Plaintiffs assert that claims pursuant to the CPA are not subsumed by the KPLA because Plaintiffs do not allege physical injury and because Plaintiffs are not seeking to impose liability on Defendants for representations made regarding a product different from the product purchased.

"As used in KRS [§§] 411.310 to 411.340, a 'product liability action' shall include any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, advertising, packaging or labeling of any product." *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky.1997) (citing KRS § 411.300(1)). "The PLA applies to all damage claims arising from the use of products, regardless of the legal theory advanced. There is no language in the PLA which suggests that products liability actions mean only those actions based on strict liability in tort under Section 402A of the Restatement of Torts. As we read the Act, if a claim is brought against a seller or a manufacturer of a product which is alleged to have caused injury, then the PLA applies, regardless of whether the action is founded on strict liability in tort, negligence or breach of warranty. While each of these theories of recovery in products liability cases requires proof of different elements and has different implications, [] their central purpose is the same: recovery of damages for injury or property damage caused by a product." *Id.*

"Under the Kentucky Consumer Protection Act, all 'unfair' acts or practices in the conduct of any trade or commerce are declared to be unlawful." *Ford Motor Co. v. Mayes*, 575 S.W.2d 480, 385 (Ky.Ct.App.1978) (citing KRS 367.170(1)). "The term 'unfair' is defined to mean 'unconscionable.' " *Id.* (citing KRS 367.170(2)). "Any person who purchases goods primarily for 'personal, family or household purposes' and who thereafter suffers any ascertainable loss as a result of any act declared unlawful by KRS 367.170 is authorized to bring a civil action to recover actual damages." *Id.* (citing KRS 367.220(1)).

Notably, the Kentucky Court of Appeals has rejected the argument that the "Consumer Protection Act, K.R.S. 367170, was not intended to create a cause of action for bodily injury: that its purpose was to protect consumers against economic loss resulting from unethical trade practices by sellers of goods and services." *AMC v. Addington*, 1984 Ky.App. LEXIS 480, *13, 1984 WL 588048 (Ky.Ct.App. Apr.

2010 WL 1530152

6, 1984). “It is generally true that if injury results from an activity declared to be statutorily unlawful, then a tort has been committed. This is so notwithstanding the fact that the primary purpose of the Kentucky Consumer Protection Act is to suppress unethical trade practices for the buying public. We consider the statute to create a degree of consumer expectation as to the safety and usability of products, encompassing some mishandling and haphazards within the definition of ordinary use of a [product].” *Id.* at *13–14. That Court elaborated,

***9** [i]t is our reasoning that if one is injured from a breach of a statutory duty, in this case the duty imposed by [K.R.S. 367.220](#)³, then that cause of action is preserved by [K.R.S. 446.070](#)⁴, which [pr]ovides that a person injured by a violation of *any* statute may recover damages. While it appears that we are letting in the back door a cause of action via [K.R.S. 446.070](#), it is only sensible that one who breaches or violates a duty imposed by law should be responsible for the consequences readily foreseeable by that failure to follow the law. The cases annotated under overwhelmingly permit recovery for personal injuries resulting from various and sundry statutory violations.

3 K.R.S. 367.220. Action for recovery of money or property—When action may be brought.

(1) Any person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice declared unlawful by [K.R.S. 367.170](#), may bring an action under the Rules of Civil Procedure in the Circuit Court in which the seller or lessor resides or has his principal place of business or is doing business, or in the Circuit Court in which the purchaser or lessee of goods or services resides, or where the transaction in question occurred, to recover actual

damages. The court may, in its discretion, award actual damages and may provide such equitable relief as it deems necessary or proper. Nothing in this subsection shall be construed to limit a person's right to seek punitive damages where appropriate.

4

K.R.S. 446.070. Penalty no bar to civil recovery.

“A person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.”

Id. The principle espoused by the Kentucky Court of Appeals appears to be the inverse of the approach adopted in New Jersey. That is, rather than the KPLA subsuming the Kentucky CPA, the expansive reach of the Kentucky CPA appears to encompass and allow for the assertion of products liability/personal injury tort claims. Therefore, with respect to Kentucky State Law, this Court will not dismiss Plaintiffs' claims on this ground.

Although foreclosed by application of the PLA in the instant case, the CFA was enacted to “protect the consumer against imposition and loss as a result of fraud and fraudulent practices by persons engaged in the sale of goods and services.” *Smith v. Alza*, 400 N.J.Super. 529, 552, 948 A.2d 686 (2008). As articulated above, the “primary purpose of the Kentucky Consumer Protection Act is to suppress unethical trade practices for the buying public.” *AMC*, 1984 Ky.App. LEXIS 480, at *13, 1984 WL 588048. The representative Plaintiff resides in Louisville, Kentucky and from 2006 to 2008 purchased Defendants' products. J & J is a New Jersey corporation engaged in business throughout the United States. Wal-Mart is an Arkansas corporation engaged in business throughout the United States. Therefore, the Kentucky State contacts in the instant matter seem to outweigh New Jersey State contacts. Kentucky State Law prevails with respect to this issue.

ii. Breach of Warranty

Defendants move to dismiss Plaintiffs' breach of implied warranty claims because the Complaint fails to allege that the products were not merchantable or failed to perform the function for which they were sold, because the Complaint only asserts a claim for a potential breach and finally, because the Complaint fails to allege a “particular purpose” separate and apart from the ordinary purpose. In contrast, Plaintiffs contend that the Complaint adequately asserts a claim of breach of implied warranty of merchantability because the

2010 WL 1530152

products are adulterated with methylene chloride and for breach of implied warranty of fitness because the goods are not fit for their ordinary and/or particular use on children.

“Contract liability for breach of warranty arises not from the common law, but from the terms of the contract and the statutory provisions of the U.C.C. The concept of implied warranty in particular is governed by two express sections of the U.C.C., [KRS 355.2–314](#) and [KRS 355.2–315](#).¹⁰” *Compex Int'l Co. v. Taylor*, 209 S.W.3d 462, 465 (Ky.2006). Pursuant to [KRS 355.2–315](#), “[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under [KRS 355.2–316](#)[, Exclusion or Modification of Warranties,] an implied warranty that the goods shall be fit for such purpose.” “Fit for ordinary purposes for which used” does not require perfection. *Bickett v. W.R. Grace & Co.*, 1972 U.S. Dist. LEXIS 14781, *22, 1972 WL 20845 (W.D.Ky.1972). “The standard is reasonable fitness for the purpose intended.” *Id.* (internal citations omitted).

*10 Pursuant to [KRS 355.2–314](#), “Goods to be merchantable must be at least as such as”

- (a) pass without objection in the trade under the contract description; and
- (b) in the case of fungible goods, are of fair average quality within the description; and
- (c) are fit for the ordinary purposes for which such goods are used; and
- (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
- (e) are adequately contained, packaged, and labeled as the agreement may require; and
- (f) conform to the promises or affirmations of fact made on the container or label if any.

Assuming, without concluding, that the descriptive messages on the alleged defective products constitute promises or affirmations, then, in accordance with the foregoing limitations, Plaintiffs' claims for breach of implied warranties pursuant to Kentucky State Law are permitted to proceed.

Although foreclosed by application of the PLA in the instant matter, the underlying purpose of the UCC as recognized by the New Jersey Supreme Court, is “to simplify, clarify and modernize the law governing commercial transactions; to permit the continued expansion of commercial practices through custom, usage and agreement of the parties; and to make uniform the law among various jurisdictions.” *N.J.S.A. 12A:1–102(1)*; *Alloway v. General Marine Indus., L.P.*, 149 N.J. 620, 630, 695 A.2d 264 (1997). Kentucky recognizes that “one of the purposes of the UCC is ‘to make uniform the law among the various jurisdictions.’” *Star Bank v. Parnell*, 992 S.W.2d 189, 192 (Ky.Ct.App.1998). Kentucky also recognizes that “[a] principal purpose of the UCC is to lower transaction costs by permitting covered parties to rely on certain objective standards of fair and reasonable dealing.” *A & A Mech. v. Thermal Equip. Sales*, 998 S.W.2d 505, 510 (Ky.Ct.App.1999). Similar to the foregoing analysis, Kentucky's contacts with the representative Plaintiff and the transactions that are the source of the Plaintiffs' claims favors the application of Kentucky State law over New Jersey with respect to this issue.

iii. Unjust Enrichment

Defendants assert that where an adequate remedy at law exists, a claim seeking equitable relief is not viable. Additionally, Defendants contend that the unjust enrichment claim cannot survive because instead of being pled in the alternative, it merely incorporates other deficient claims set forth in the Complaint. Finally, Defendants argue that because Plaintiffs fail to assert that the allegedly defective products failed to perform the function for which they were sold, a claim for unjust enrichment cannot survive. By contrast, Plaintiffs assert that non-gratuitous benefits were conferred upon Defendant, the retention of which would unjustly enrich the Defendants.

“A party may state as many separate claims or defenses as it has, regardless of consistency.” *Holley Performance Products v. Keystone Auto Operations, Inc.*, 2009 U.S. Dist. LEXIS 102709, *16, 2009 WL 3613735 (W.D.Ky. Oct. 29, 2009). In *Holley*, the Court concluded that “as this is a motion to dismiss, and not for summary judgment, the burden on the plaintiff is only to allege sufficient facts to show unjust enrichment is a plausible claim for relief.” *Id.* (“The Court need not at this time determine whether or not there is in fact a viable contract claim which destroys any claims for equitable relief; the Court need only determine if all claims are sufficiently plead.”). “Under Kentucky law, to succeed on a claim of unjust enrichment,

the plaintiff must show the following elements: (1) a benefit conferred upon the defendant at the plaintiff's expense; (2) a resulting appreciation of the benefit by the defendant, and (3) an inequitable retention of the benefit without payment for its value." *Stonestreet Farm, LLC v. Buckram Oaks Holdings, N.V.*, 2007 U.S. Dist. LEXIS 31313, *15, 2007 WL 6995056 (E.D.Ky. Apr. 16, 2007) (citing *Guarantee Electric v. Bog Rivers Electric Corp.*, 669 F.Supp. 1371, 1381 (W.D.Ky.1987)). Equitable remedies are only available where legal remedies are insufficient. *Holley*, 2009 U.S. Dist. LEXIS 102709, at *7, 2009 WL 3613735 (citing *Dairy Queen, Inc. v. Wood*, 369 U.S. 469, 478, 82 S.Ct. 894, 8 L.Ed.2d 44 (1962)).

*11 Plaintiffs claim to have conferred a non-gratuitous benefit upon Defendants. Consistent with the elements of a claim for unjust enrichment, it is unclear to the Court how a non-gratuitous benefit is incurred at the expense of Plaintiffs.

Nonetheless, Plaintiffs allege exclusively economic injury. On this ground, there is no indication that an adequate remedy at law is unavailable to Plaintiffs. Therefore, to the extent that Plaintiffs assert a claim for unjust enrichment pursuant to Kentucky State Law, Plaintiffs' Complaint is dismissed.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion is **granted in part** and **denied in part**. Plaintiffs' Complaint is **partially dismissed without prejudice** pursuant to **Fed.R.Civ.P. 12(b)(1)** and **Fed.R.Civ.P. 12(b)(6)**. An appropriate Order accompanies this Opinion.

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TAB 13

2020 WL 3546750

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NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Lory D'ADDARIO and Peter D'Addario, Plaintiffs,

v.

JOHNSON & JOHNSON; Ethicon, Inc.;
and Mentor Worldwide, LLC, Defendants.

Civil Action No. 19-15627 (MAS) (TJB)

Filed 06/30/2020

Attorneys and Law Firms

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MEMORANDUM OPINION

SHIPP, District Judge

*1 This matter comes before the Court upon Defendants Mentor Worldwide, LLC (“Mentor”), Ethicon, Inc. (“Ethicon”), and Johnson & Johnson’s (collectively, “Defendants”) Motion to Dismiss. (ECF No. 6.) Plaintiffs Lory D’Addario (“D’Addario”) and Peter D’Addario (collectively, “Plaintiffs”) opposed (ECF No. 25), and Defendants replied (ECF No. 26).¹ The Court has carefully considered the parties’ submissions and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth below, Defendants’ Motion is granted.

¹ Defendants filed a notice of supplemental authority, alerting the Court to three “district court decisions granting Mentor’s motions to dismiss in nearly identical cases.” (ECF No. 27.) Plaintiffs replied to Defendants’ notice. (ECF No. 28.) Thereafter, Defendants filed an additional notice of supplemental authority on another “district court decision granting Mentor’s motion to dismiss in a nearly identical case.” (ECF No. 29.)

I. BACKGROUND²

² The Court accepts all well-pleaded factual allegations as true. See *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008).

On June 14, 2013, the United States Food and Drug Administration (“FDA”) approved Mentor’s premarket approval application for its MemoryShape breast implants (hereinafter, “Mentor Breast Implants”). (Compl. ¶¶ 74, 218, ECF No. 1.) Defendants design, manufacture, market, label, and distribute Mentor Breast Implants. (*Id.* ¶ 1.)

In July 2015, D’Addario underwent breast reconstruction surgery and received Mentor Implants. (*Id.* ¶ 152.) Plaintiffs allege that, at that time, Defendants were aware that Mentor Implants caused breast implant-associated anaplastic large cell lymphoma (“BIA-ALCL”) but failed to advise D’Addario of the risk. (*Id.* ¶¶ 73, 153–55.) Had D’Addario known of the slightest risk of BIA-ALCL, she would not have proceeded with the implantation. (*Id.* ¶ 156.)

In July 2017, D’Addario tested positive for BIA-ALCL. (*Id.* ¶ 158.) Following diagnosis and treatment of BIA-ALCL, D’Addario suffered pain, swelling, and embarrassment. (*Id.* ¶ 161.) In August 2017, D’Addario underwent implant removal and total capsulectomy. (*Id.* ¶ 159.) The explantation caused D’Addario tremendous pain. (*Id.* ¶ 160.)

Plaintiffs bring the following Counts against Defendants: (1) Strict Liability—Manufacturing Defect in violation of the Connecticut Product Liability Act (“CPLA”), Conn. Gen. Stat. §§ 52-572, *et seq.*; (2) Negligent Misrepresentation; (3) Breach of Express and Implied Warranty; (4) Violation of the Connecticut Unfair Trade Practices Act (“CUTPA”), Conn. Gen. Stat. §§ 42-110b, *et seq.*; and (5) Loss of Consortium. (*Id.* ¶¶ 176–233.)

II. LEGAL STANDARD

“Federal Rule of Civil Procedure 8(a)(2) requires only ‘a short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to ‘give the defendant fair notice of what the ... claim is and the grounds upon which it rests.’” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)) (alteration in original).

² District courts undertake a three-part analysis when considering a motion to dismiss pursuant to Federal Rule

of Civil Procedure 12(b)(6). *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). “First, the court must ‘tak[e] note of the elements a plaintiff must plead to state a claim.’ ” *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)) (alteration in original). Second, the court must accept as true all of the plaintiff’s well-pled factual allegations and “construe the complaint in the light most favorable to the plaintiff.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (internal quotations and citation omitted). In doing so, the court is free to ignore legal conclusions or factually unsupported accusations that merely state, “the-defendant-unlawfully-harmed-me.” *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Finally, the court must determine whether “the facts alleged in the complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’ ” *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). “The defendant bears the burden of showing that no claim has been presented.” *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005).

III. DISCUSSION

Defendants make the following arguments for the dismissal of Plaintiffs’ Complaint: (1) Counts Two through Four are subsumed by the CPLA (Defs.’ Moving Br. 10–12); (2) Plaintiffs’ product liability claims are preempted by federal law (*id.* at 13–36); (3) Plaintiffs’ claims do not satisfy applicable pleading requirements (*id.* at 36–40); and (4) Plaintiffs’ loss of consortium claim fails because it is a derivative claim. The Court addresses each argument in turn.

A. CPLA Subsumption³

³ Under New Jersey’s “most significant relationship” test, where plaintiffs assert product liability claims, the plaintiffs’ home state has the “most significant relationship” to the issues. *Arlanson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 699 (D.N.J. 2011) (citing *P.V. v. Camp Jaycee*, 962 A.2d 453 (N.J. 2008)). Here, the Court applies the law of Plaintiffs’ home state of Connecticut to Plaintiffs’ product liability claims, which the parties do not dispute. (Defs.’ Moving Br. 7, ECF No. 6; Pls.’ Opp’n Br. 5, ECF No. 25.)

Defendants argue that Counts Two through Four of the Complaint are subsumed by the CPLA. (*Id.* at 10.) The CPLA provides the exclusive vehicle in Connecticut for actions premised on “harm caused by a product.” Conn. Gen. Stat. § 52–572n(a) (“A product liability claim ... shall be in lieu of

all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product.”). The provision essentially consolidates all product liability claims into a “single form of action.” *LaMontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846, 855 (2d Cir. 1994) (citing *Winslow v. Lewis-Shepard, Inc.*, 562 A.2d 517, 521 (Conn. 1989)).

Here, the Court finds—and Plaintiffs agree (Pls.’ Opp’n Br. 34)—that Counts Two and Three alleging negligent misrepresentation and breach of express and implied warranty are subsumed by the CPLA. Although the two claims are dismissed, Plaintiffs may, nonetheless, assert these common law theories of products liability under Count One, their CPLA claim. *Fraser v. Wyeth, Inc.*, 857 F. Supp. 2d 244, 252 (D. Conn. 2012) (“A plaintiff bringing a cause of action under the CPLA therefore retains the right to allege traditional theories of recovery under one unified CPLA claim.” (citation omitted)).

Next, the Court turns to Plaintiffs’ CUTPA claim. The CPLA will not bar a CUTPA claim if an injury was not caused by a defective product or if the plaintiffs are not pursuing a claim for “personal injury, death or property damage.” *Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769, 774 (Conn. 2003) (quoting Conn. Gen. Stat. § 52-572m(b)). In other words, where the plaintiffs’ CUTPA claim seeks “to redress merely a financial injury suffered ... of a kind that has never been regarded as part of the traditional tort remedy for harm caused by a defective product,” the CUTPA claim is not barred. *Id.* at 775.

*3 Plaintiffs’ characterization of D’Addario’s injuries as “financial” in nature belies their true nature as harms caused by a defective product. (See Pls.’ Opp’n Br. 23–24.) Plaintiffs allege that, because of Defendants’ deceptive trade practices, she suffers from permanent and continuing injuries, which “require medical treatment and hospital expenses” and “lost ... financial gains.” (Compl. ¶ 228.) The Court, however, fails to distinguish between the injuries Plaintiffs allege and those typically asserted in garden-variety products liability suits. The Court, therefore, dismisses Plaintiffs’ CUTPA claim as barred by the CPLA’s exclusivity provision. For these reasons, the Court dismisses Counts Two, Three, and Four as subsumed by the CPLA.

B. Federal Preemption

Defendants argue that Plaintiffs’ state-law claims are either expressly or impliedly preempted by federal law. (Defs.’

Moving Br. 13–36.) Defendants also argue that certain claims fail because Plaintiffs have not alleged parallel state-law duties (*id.* at 28–36) or causal nexuses between her injuries and Defendants' alleged violations (*id.* at 36).

The Medical Device Amendments of 1976 (“MDA”) to the Federal Food Drug & Cosmetic Act, 21 U.S.C. §§ 360c, *et seq.*, “imposed a regime of detailed federal oversight” for medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316, 319 (2008). Of the devices regulated under the MDA, Class III devices that undergo the “premarket approval” process receive the greatest oversight. *Id.* at 317. The premarket approval process is “rigorous” and “includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A).” *Id.* at 317–18.

Premarket approval further imposes “requirements” that are “specific to a medical device.” *Id.* at 323–24. Devices are “to be made with almost no deviations from the specifications in its approval application.” *Id.* at 323. “Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.” *Id.* at 319 (citing § 360e(d)(6)(A)(i)).

To determine whether the MDA expressly preempts a state claim under § 360k(a), courts consider (1) whether the FDA has established “requirements” applicable to the specific device at issue; and if so, (2) whether the plaintiffs' claims are based on state requirements that are “different from, or in addition to,” the federal ones and that “relate to safety and effectiveness.” *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 (3d Cir. 2018) (citing *Riegel*, 552 U.S. at 321–22). If the answer is yes to both questions, the state claim is preempted. *Id.* “If, instead, the answer to the second question is no, then the state duties in such a case parallel, rather than add to, federal requirements, and the claims are not preempted.” *Id.* (citation omitted) (internal quotation marks omitted).

Even if a state-law claim is not expressly preempted, it may be impliedly preempted under § 337(a). Under the MDA, all actions to enforce FDA requirements “shall be by and in the name of the United States.” 21 U.S.C. § 337(a). “[T]he Federal Government rather than private litigants ... are authorized to file suit for noncompliance with

the medical device provisions.” *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001). To that end, the *Buckman* Court held that “state-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administrations judgment and objectives” and are impliedly preempted by the MDA. *Id.* at 350.

*4 Ultimately, where a state-law claim for violating a state-law duty “parallels” a federal-law duty under the MDA, the MDA will not preempt the state-law claim. *Riegel*, 552 U.S. at 330. It is not enough to state that a state law parallels federal law generally. Plaintiffs must also allege a link between a product's deviation from an FDA requirement and the alleged injury. *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 598 (D.N.J. 2015); *see Simoneau v. Stryker Corp.*, No. 13-1200, 2014 WL 1289426, at *10 (D. Conn. Mar. 31, 2014) (dismissing a plaintiff's misbranding, failure to warn, and failure to report claims for failure to link her injury to a violation of an FDA requirement).

Here, it is undisputed that Mentor *Breast Implants* received premarket approval. (Compl. ¶ 74.) It is also undisputed that the first part of the *Riegel* preemption analysis is satisfied. (Pls.' Opp'n Br. 18.) The Court, therefore, only considers the second part of the *Riegel* test—whether Plaintiffs' state-law claims would impose requirements that are “different from or in addition to” federal safety and effectiveness requirements.

1. Strict Product Liability—Manufacturing Defect

Plaintiffs allege that “Mentor *Breast Implants* were manufactured in a flawed manner that violated the FDA approved design standards and specifications.” (Compl. ¶ 178.) Plaintiffs allege that the *breast implants* she received were manufactured in a non-conforming manner because they “contained a graham-negative biofilm/endotoxin released from the surface of the textured surface which stimulates *lymphocytes*” (Compl. ¶ 180), and that these “bacteria stimulating *lymphocytes*” caused D'Addario's BIA-ALCL (*id.* ¶ 182).

Plaintiffs do not, however, allege that the FDA required the exclusion of this endotoxin. If a federal requirement is not properly identified, the Court is unable to determine whether Plaintiffs' state-law claim based upon Connecticut requirements is “different from, or in addition to,” the federal ones, that relate to safety and effectiveness. *Mendez v. Shah*,

94 F. Supp. 3d 633, 639 (D.N.J. 2015). Moreover, although Plaintiffs broadly allege that Defendants “failed to adhere to [numerous] federal specifications” (e.g., Compl. ¶ 184a-e), Plaintiffs fail to allege how these violations resulted in the presence of lymphocytes in her implants or any other injury. Plaintiffs’ manufacturing defect claim is, accordingly, dismissed.

To the extent Plaintiffs now base their manufacturing defect claim on violations of FDA’s Current Good Manufacturing Practices (*see* Pls.’ Opp’n Br. 9, 17–18), these allegations are improperly pleaded in the opposition brief. “[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.” *Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (citation omitted). Because the Court grants Plaintiffs leave to amend the Complaint, Plaintiffs may further flush out this theory in an amended complaint.

2. Failure to Warn

The contours of Plaintiffs’ failure-to-warn claim are unclear, as allegations that could potentially support such a claim are scattered throughout the Complaint. (*See generally* Compl.) Nonetheless, liberally construing the Complaint, the Court identifies the following two theories: (1) Defendants failed to warn “consumers, healthcare providers, the general public, and the FDA that ALCL or BIA-ALCL … was a potential risk of Mentor *Breast Implants*, and that hundreds, if not thousands, of patients had suffered negative experiences and events as a result of such known risk” (Compl. ¶ 117); and (2) Defendants failed to warn D’Addario “of the defective and unreasonably dangerous conditions of its Mentor *Breast Implants* that could cause serious injury or death and to timely and accurately report such adverse events to the FDA” (*id.* ¶ 179).

*5 To the extent Plaintiffs take issue with the original warning Mentor provided to “consumers, [including D’Addario], healthcare providers. [and] the general public” (Compl. ¶ 117), this claim is preempted. A device’s “proposed labeling” is reviewed during the PMA process and a manufacturer may not revise the labeling without FDA permission. *Riegel*, 552 U.S. at 318–19. “[S]tate claims based on labeling defects such as false or missing information about health risks … are[, therefore,] preempted in the case of Class III medical devices, because these claims necessarily impose requirements different from or additional

to the FDA’s requirements.” *Simoneau*, 2014 WL 1289426, at *11; *see also* *Horn v. Thoratec Corp.*, 376 F.3d 163, 176 (3d Cir. 2004) (finding a plaintiff’s state-law claims would add to the requirements imposed by the FDA on device labeling). Because Plaintiffs’ claim would require Mentor to provide different warnings or instructions from those initially approved by the FDA, the claim is preempted.

To the extent Plaintiffs challenge the information Mentor provided to the FDA in its premarket approval application (Compl. ¶ 117), Plaintiffs “identif[y] no separate state law duty to warn the FDA.” *Simoneau*, 2014 WL 1289426, at *11. Moreover, such a claim fundamentally alleges fraud-on-the-FDA and would be impliedly preempted under *Buckman*. For these reasons, the Court dismisses Plaintiffs’ failure-to-warn claim.

3. Negligent Misrepresentation

Plaintiffs allege that Defendants “negligently misrepresented material information regarding their product including, but not limited to, its safety.” (Compl. ¶ 202.) According to Plaintiffs, “Defendants knew or should have known that their *breast implants* were not actually safe as they were manufactured in a defective condition.” (*Id.* ¶ 203.) Plaintiffs allege that “[D’Addario] was[, therefore,] unaware and ignorant of the falsity of the statements and reasonably … relied upon them and believed them to be true.” (*Id.* ¶ 204.)

Here, Plaintiffs’ negligent misrepresentation claim fails because they wholly fail to set forth a relevant federal requirement. To the extent Plaintiffs’ claim is based on defective manufacturing, the Court reiterates that Plaintiffs fail to allege a violation of a federal requirement on this basis. *See supra* Section III.B.2. Plaintiffs’ negligent misrepresentation claim is dismissed.

4. Breach of Implied and Express Warranty

The Complaint alleges that “Mentor *Breast Implants* do not conform to … implied or express warranties and representations because [they] are not safe or effective for their ordinary purpose, nor are they safer or more effective than other *breast implants* available, [and] they were not manufactured in the specifications required by the FDA.” (Compl. ¶ 220; *see also id.* ¶¶ 213–16, 221.)

Here, again, Plaintiffs' breach of warranty claim based on device safety and effectiveness fails because Plaintiffs fail to allege a violation of a federal regulation. *Supra* Section III.B.2. Furthermore, Plaintiffs' breach of warranty claim essentially challenges the safety and effectiveness of Mentor *Breast Implants*, and, to find for Plaintiffs, the Court would necessarily contradict the FDA's determination of safety and effectiveness during premarket approval. Plaintiffs' breach of express and implied warranty claim is, accordingly, dismissed.

C. Group Pleading

Defendants argue that Plaintiffs make "the same conclusory and generic allegation against each defendant—i.e., that each defendant is responsible for 'designing, formulating, testing, packaging, labeling, producing, assembling, advertising, marketing, promoting, distributing, manufacturing, and selling' " Mentor *Breast Implants*. (Defs.' Moving Br. 37 (quoting Compl. ¶ 22).) According to Defendants, by "lumping" together their alleged misconduct, Plaintiffs fail to provide fair notice of the basis of their claims as against each individual defendant. (*Id.*) Defendants further argue that, although Plaintiffs allege that Johnson & Johnson and Ethicon are "agents" or "alter-egos" of Mentor or that Johnson & Johnson "controlled" Mentor, Plaintiffs fail to allege facts that support these theories. (*Id.* at 38–39.) Plaintiffs argue that they have fulfilled their duty at this pleading stage—pointing to allegations that Johnson & Johnson has owned Mentor since 2009 and that Johnson & Johnson and Ethicon admitted they are "combining forces" with Mentor. (Pls.' Opp'n Br. 37–38.)

*6 Plaintiffs' Complaint broadly alleges Defendants' misconduct but fails to allege the conduct for which each defendant is culpable. "Courts in this district generally agree that this type of 'group pleading' does not satisfy Rule 8, because it does not place Defendants on notice of the claims against each of them." *Sheeran v. Blyth Shipholding S.A.*, No. 14-5482, 2015 WL 9048979, at *3 (D.N.J. Dec. 16, 2015). Moreover, the lack of well-pleaded facts does not allow the

Court "to draw the reasonable inference that [each] defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

Plaintiffs, accordingly, have not alleged sufficient facts to identify each defendant's role with the Mentor *Breast Implants*. It is not enough to say that "each of the defendants is responsible for everything." *Sheeran*, 2015 WL 9048979, at *5. Nor does the *In re Riddell Concussion Reduction Litigation*, 77 F. Supp. 3d 422 (D.N.J. 2015) decision mandate a contrary conclusion. There, the plaintiffs alleged that the defendant entities took concerted action and "operat[ed] under a single brand." *Id.* at 431–32. Plaintiffs make no such allegations as to Defendants here. (See generally Compl.) Because Counts One through Five are directed to each of the Defendants, they are dismissed without prejudice.

D. Plaintiffs' Loss-of-Consortium Claim Fails

Because a loss of consortium claim is a derivative claim and because D'Addario fails to assert a product liability claim, Peter D'Addario's loss of consortium claim fails as a matter of law and must be dismissed. *Jacoby v. Brinckerhoff*, 735 A.2d 347, 352 (Conn. 1999) (Finding a "plaintiff cannot pursue an action for loss of consortium in the absence of any basis in the record for a finding that his ... spouse was injured as a result of her treatment by the defendant"); see also *O'Dell v. Greenwich Healthcare Servs., Inc.*, No. CV116008364S, 2013 WL 2278752, at *5 (Conn. Super. Ct. Apr. 25, 2013).

IV. CONCLUSION

For these reasons, the Court grants Defendants' Motion to Dismiss. The Complaint is dismissed without prejudice subject to the filing of an amended complaint. The Court will enter an Order consistent with this Memorandum Opinion.

All Citations

Slip Copy, 2020 WL 3546750

TAB 14

686 Fed.Appx. 101

This case was not selected for publication in West's Federal Reporter.

See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also U.S.Ct. of Appeals 3rd Cir. App. I, IOP 5.1, 5.3, and 5.7. United States Court of Appeals, Third Circuit.

David DANON, Appellant

v.

VANGUARD GROUP, INC.

No. 16-2881

Submitted under Third Circuit LAR 34.1(a) on January 26, 2017

(Opinion filed: April 12, 2017)

Synopsis

Background: Former employee sued former employer alleging violations of Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act, and Pennsylvania whistleblower law, The United States District Court for the Eastern District of Pennsylvania, *C. Darnell Jones, II, J., 2016 WL 2988987*, dismissed action. Former employee appealed.

[Holding:] The Court of Appeals, *Roth*, Circuit Judge, held that New York case did not preclude former employee's federal suit, where federal complaint did not suffer from same defect as state case.

Vacated in part and remanded.

Procedural Posture(s): On Appeal.

West Headnotes (2)

[1] Judgment **Matters which were not or could not have been adjudicated**

Former employee was not precluded under issue preclusion doctrine from asserting that former employer knew about his activities in federal

suit alleging violations of Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act, and Pennsylvania whistleblower law, where issue decided in prior New York case was whether employee's complaint adequately alleged facts regarding employer's knowledge of his whistleblowing activities. *15 U.S.C.A. § 78u-6(h)(1); 18 U.S.C.A. § 1514A; 43 P.S. § 1423.*

2 Cases that cite this headnote

[2] Judgment **Dismissal and nonsuit**

Judgment **Matters which were not or could not have been adjudicated**

Federal complaint, which did allege knowledge on part of former employer in suit by former employee alleging violations of Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act, and Pennsylvania whistleblower law, was not precluded by prior New York decision, which affirmed dismissal for failure to adequately plead knowledge of employee's allegedly protected conduct. *15 U.S.C.A. § 78u-6(h)(1); 18 U.S.C.A. § 1514A; 43 P.S. § 1423.*

1 Cases that cite this headnote

***102** On Appeal from the United States District Court for the Eastern District of Pennsylvania (D. C. Civil Action No. 2-15-cv-06864), District Judge: Honorable *C. Darnell Jones, II*

Attorneys and Law Firms

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Stephen G. Yoder, Esq., United States Securities & Exchange Commission, Washington, DC, for Amicus Appellant Securities & Exchange Commission

OPINION *

* This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

ROTH, Circuit Judge

David Danon used to work as a tax lawyer for The Vanguard Group, Inc., an investment services firm. He came to believe that Vanguard was violating certain tax and corporate laws, and he informed various senior employees of Vanguard of this belief. Vanguard's officers disagreed with Danon's assessment of the law, but Danon continued to inform Vanguard employees of his legal conclusions. Three years later, Vanguard terminated his employment. He then sued Vanguard in New York state court, specifying numerous causes of action, one of which was retaliation. However, his case was dismissed because, as relevant here, it did not adequately plead facts relating to Vanguard's knowledge of Danon's activities. He has now sued Vanguard for retaliation under several different statutes in federal court, but his case was dismissed again—this time because, among other reasons, he was precluded from asserting that Vanguard knew about his activities. He has now appealed that dismissal, arguing that he is not precluded. For the reasons that follow, we agree. However, because he has not appealed with respect to any other issue, and because the District Court provided sufficient alternative grounds for dismissing all of Danon's claims except the Dodd-Frank claim, we will vacate only the dismissal of the Dodd-Frank claim.

I. Background

In 2010, Danon, while working as a tax lawyer for Vanguard, came to the conclusion *103 that Vanguard was engaged in illegal tax and corporate practices. He alleges that, beginning at that time and continuing throughout the remainder of his employment with Vanguard, he advised various senior corporate employees and members of Vanguard's tax department of his conclusion. However, these individuals rejected his conclusion. He alleges that Vanguard's senior employees told him to stop attempting to notify individuals at Vanguard of his conclusion and not to put this conclusion in writing. In addition, he alleges that, around this time, a Vanguard employee requested that Danon perform certain

duties (which he does not specify) that Danon refused to perform because he believed they were in violation of the law. On or around January 3, 2013, Vanguard informed Danon that it was going to terminate his employment soon and that he should seek other employment. Vanguard ultimately terminated his employment in June 2013.

Shortly before his termination, on May 8, 2013, Danon filed an action against Vanguard with the Supreme Court of New York in New York County. Among other causes of action, he suggested that Vanguard retaliated against him by firing him for his efforts to stop Vanguard's illegal activities, and that this retaliation violated the New York False Claims Act. Upon Vanguard's motion, his complaint was dismissed. The court held that the complaint failed to allege a claim for retaliation under the statute because it did not "contain any allegations that [Vanguard] knew in January 2013[] that Danon was involved in protected conduct." While he repeatedly stressed that Vanguard knew about his conduct, he did "not indicate the dates when he expressed his concerns to Vanguard's employees and, in particular, whether he did so before he was informed of his termination in January 2013."¹ Because knowledge was a necessary element of Danon's claim, failing to plead knowledge adequately was sufficient to warrant dismissal.

¹ App. 174.

While Danon was appealing that dismissal, he filed this suit against Vanguard in the United States District Court for the Eastern District of Pennsylvania. He claimed that his termination was retaliation in violation of the whistleblower protections of the Sarbanes-Oxley Act,² the Dodd-Frank Wall Street Reform and Consumer Protection Act,³ and the Pennsylvania Whistleblower Law.⁴ Vanguard moved to dismiss on the basis of, among other things, issue preclusion and failure to provide sufficient factual allegations to support the claim for retaliation.⁵ The District Court held that issue preclusion applied and defeated Danon's claims.⁶ The District Court also held that the Pennsylvania Whistleblower Law claim was time-barred because Danon did not bring his claim within 180 days after occurrence of the alleged violation, as required by the statute, and the Sarbanes-Oxley claim was barred because it was not administratively exhausted with the Occupational Safety and Health Administration, as required by the statute.⁷

2017 IER Cases 119,585

2 18 U.S.C. § 1514A.

3 15 U.S.C. § 78u-6(h)(1).

4 43 P.S. § 1423.

5 Because the District Court did not decide whether the complaint provided sufficient factual allegations to support the claim, we do not decide that issue here either.

6 *Danon v. Vanguard Grp., Inc.*, No. 15-6864, 2016 WL 2988987, at *3-*4 (E.D. Pa. May 23, 2016).

7 *Id.* at *6. Danon has not appealed these determinations.

This appeal followed.

*104 II. Discussion⁸

8 The District Court had jurisdiction under 28 U.S.C. § 1331. We have jurisdiction under 28 U.S.C. § 1291. Our review over a District Court's grant of a motion to dismiss on the basis of issue preclusion is generally plenary. *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 248 (3d Cir. 2006).

The District Court held that Danon was precluded "from relitigating whether there was a causal connection between his firing and his activities, even if such activities are protected. As a causal connection is a component of the *prima facie* case for retaliation claims under SOX, Dodd-Frank, and the Pennsylvania Whistleblower Law, Plaintiff's Complaint must be dismissed."

The District Court held that a New York state court case gave rise to preclusion here. "[A] federal court must give to a state-court judgment the same preclusive effect as would be given that judgment under the law of the State in which the judgment was rendered."⁹ Hence, we look to New York law to determine whether Danon would be precluded in this suit. Under New York law, issue preclusion prevents a party from relitigating an issue that was decided in an earlier proceeding.¹⁰ For preclusion to apply, "[t]here must be an identity of issue which has necessarily been decided in the prior action and is decisive of the present action, and, second,

there must have been a full and fair opportunity to contest the decision now said to be controlling."¹¹

9 *Migra v. Warren City Sch. Dist. Bd. of Educ.*, 465 U.S. 75, 81, 104 S.Ct. 892, 79 L.Ed.2d 56 (1984).

10 *Atl. Mut. Ins. Co. v. Lauria*, 291 A.D.2d 492, 739 N.Y.S.2d 394, 396 (2002).

11 *Schwartz v. Pub. Adm'r of Bronx Cty.*, 24 N.Y.2d 65, 298 N.Y.S.2d 955, 246 N.E.2d 725, 729 (1969). See also *PenneCom B.V. v. Merrill Lynch & Co.*, 372 F.3d 488, 491 (2d Cir. 2004) (quoting *Schwartz* to describe New York issue preclusion).

[1] [2] The issue that was decided in the New York case was whether Danon's complaint adequately alleged facts regarding Vanguard's knowledge of Danon's whistleblowing activities. The court did not decide whether, in fact, Vanguard knew about Danon's activities.¹² Hence, Danon is not precluded from asserting that Vanguard knew about Danon's activities in this case; that factual issue was not decided. More generally, the New York decision can give rise to issue preclusion only insofar as Danon's complaint suffers from the same defects as the New York complaint did.¹³ The federal complaint does allege knowledge, so it does not suffer from the same defect.¹⁴ For this reason, we will vacate the issue preclusion portion of the District Court's opinion.

12 App. 173-75.

13 *175 E. 74th Corp. v. Hartford Acc. & Indem. Co.*, 51 N.Y.2d 585, 435 N.Y.S.2d 584, 416 N.E.2d 584, 586 n.1 (1980) ("A dismissal [for failure to state a cause of action] has preclusive effect only as to a new complaint for the same cause of action which fails to correct the defect or supply the omission determined to exist in the earlier complaint.").

14 In determining that the federal complaint alleges knowledge, we are not deciding whether those allegations are appropriate or sufficient. We leave that determination to the District Court.

III. Conclusion

For the foregoing reasons, we will vacate the portion of the District Court's opinion dismissing the Dodd-Frank claim

2017 IER Cases 119,585

and remand for further proceedings consistent with this opinion.¹⁵

¹⁵ The parties raised additional arguments regarding the Dodd-Frank claim before this Court. The District Court, however, is better situated to rule on

these claims in the first instance. Thus, we will not resolve them here.

All Citations

686 Fed.Appx. 101, 2017 IER Cases 119,585

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TAB 15

2006 WL 1373230

United States District Court, D. New Jersey.

Craig P. DONOVAN, et al., Plaintiffs,

v.

The PUBLIC POLICY CENTER OF
NEW JERSEY, et al., Defendants.

Civil Action No. 05-1181 (MLC).

May 17, 2006.

Attorneys and Law Firms

[Kimberly G. Jinks](#), Markowitz Gravelle, LLP, Lawrenceville, NJ, for Plaintiffs.

[Michael A. Cifelli](#), Scarinci & Hollenbeck LLC, Lyndhurst, NJ, for Defendants.

MEMORANDUM OPINION

[COOPER](#), District Judge.

*1 The defendants, the Public Policy Center of New Jersey (“PPCNJ”), Mark J. Magyar (“Magyar”), Sharon L. Naeloe (“Naeloe”), W. Michael Murphy, Jr. (“Murphy”), Judith Shaw (“Shaw”), Richard H. Bagger, Michael F. Candwell, Susan A. Cole, Ellen M. Dotto, William G. Dressel, Jr., Joseph E. Gonzales, Jr., Jeannine LaRue, Roger E. Nutt, James Morford, James E. Schroeder, Robert G. Sommer, John Torok, Joan C. Verplanck, Sharon L. Weiner, Melanie Willoughby, and Ronald Applebaum (collectively, the “defendants”) move to dismiss the complaint filed by the plaintiffs, Craig P. Donovan (“Donovan”) and Linda J. Holaday (“Holaday”) (collectively, the “plaintiffs”), for (1) failure to state a claim upon which relief may be granted, pursuant to [Federal Rule of Civil Procedure \(“Rule”\)](#) 12(b)(6), and (2) lack of subject matter jurisdiction, pursuant to [Rules 12\(b\)\(1\) and 12\(h\)\(3\)](#).¹ The Court, for the reasons stated herein, will deny the motion.

¹ Laurence M. Downes (“Downes”) is a named defendant in the action and has been served with a copy of the complaint. (Dkt. entry no. 37, 2-21-06 Aff. of Serv.) However, no counsel has properly entered an appearance on his behalf. (See Dkt. entry no. 40, 3-16-06 Stipulation.) Counsel for the

other defendants has not indicated that they also represent Downes.

BACKGROUND

The plaintiffs are two former employees of PPCNJ. Magyar founded PPCNJ on or about September 1, 2001, to serve as a “nonprofit organization with missions and programs geared toward the public’s education of policy issues facing New Jersey’s citizens.” (Compl., at ¶¶ 38, 40.) PPCNJ publishes, *inter alia*, the New Jersey Reporter (the “Reporter”) and the New Jersey Heritage magazines. (*Id.* at ¶ 39.)

PPCNJ hired Holaday to serve as the “full-time Marketing Director ... when it opened its doors on or about September 1, 2001.” (*Id.* at ¶ 52.) PPCNJ employed Holaday at a salary of \$40,000 annually, plus reimbursement of out-of-pocket expenses. (*Id.* at ¶¶ 32, 53.) As Marketing Director, Holaday was assigned responsibility for PPCNJ’s marketing, and she (1) edited photography for all of PPCNJ’s publications, and (2) attended and participated in conferences and staff meetings. (*Id.* at ¶ 54.) Holaday voluntarily terminated her employment with PPCNJ effective November 4, 2003. (*Id.* at ¶ 55.)

PPCNJ hired Donovan as its Vice President of Policy and Research, and he “began working in that capacity ... on or about September 1, 2001.” (*Id.* at ¶ 57.) PPCNJ employed Donovan at a salary of \$25,000 annually, plus reimbursement of out-of-pocket expenses. (*Id.* at ¶¶ 31, 58.) Donovan worked at PPCNJ part-time, for approximately 20–25 hours per week. (*Id.* at ¶ 59.) Donovan’s employment at PPCNJ supplemented his full-time position as a college professor. (*Id.* at ¶ 64.)

As Vice President of Policy and Research, Donovan was primarily responsible for writing and editing articles for publication in the Reporter and on the Internet. (*Id.* at ¶ 60.) In this regard,

[h]is efforts were focused on supporting and developing PPCNJ’s work, by analyzing public policy issues, providing research to support such work, promoting public awareness and participation in the analyses and discussions of major issues relating to New Jersey and its citizens, and writing columns

or articles about such issues in each edition of the Reporter. He also attended and participated in conferences and regular staff meetings.

*2 (*Id.*) Donovan voluntarily terminated his employment with PPCNJ on or about December 1, 2003.

The plaintiffs brought this action alleging that the defendants—in particular, PPCNJ—failed to pay their earned wages or reimburse them for expenses incurred while working for PPCNJ. (Compl., at ¶¶ 30, 37, 73–75.) The plaintiffs assert that the defendants violated the (1) Fair Labor Standards Act (“FLSA”), (2) New Jersey State Wage and Hour Law (“NJWHL”), and (3) New Jersey State Wage Payment Law (“NJWPL”). (*Id.* at ¶¶ 77–107.) The plaintiffs also assert claims for breach of contract and quantum meruit. (*Id.* at ¶¶ 108–135.) The defendants moved to dismiss on December 1, 2005, claiming that (1) the plaintiffs failed to state a claim upon which relief may be granted, pursuant to Rule 12(b)(6), and (2) the Court lacked subject matter jurisdiction, pursuant to Rules 12(b)(1) and 12(h)(3). (Dkt. entry no. 28.)

DISCUSSION

I. Standard Of Review For A 12(b)(6) Motion

A complaint may be dismissed for “failure to state a claim upon which relief can be granted.” Fed.R.Civ.P. 12(b)(6). On a motion to dismiss, the Court must accept as true all of the factual allegations in the complaint, and draw all reasonable inferences in favor of the plaintiff. *Doe v. Delie*, 257 F.3d 309, 313 (3d Cir. 2001). But a court need not credit a complaint’s “bald assertions” or “legal conclusions” when deciding a motion to dismiss. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429–30 (3d Cir.1997) (citation omitted). “Dismissal of claims under Rule 12(b)(6) is appropriate only if it appears beyond doubt that the plaintiff can prove no set of facts in support of [the] claim upon which relief may be granted.” *Jakomas v. McFalls*, 229 F.Supp.2d 412, 419 (W.D.Pa.2002).

The Court, when considering a motion to dismiss, may generally not “consider matters extraneous to the pleadings.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426. However, if the Court exercises discretion and permits a party to present matters outside the pleadings, the Court must

(1) convert the motion to dismiss into one for summary judgment, and (2) allow the parties a reasonable opportunity to present all material pertinent to such a motion under Rule 56. Fed.R.Civ.P. 12(b). An exception to this general rule is that the Court may consider (1) exhibits attached to the complaint, (2) matters of public record, and (3) all documents that are integral to or explicitly relied upon in the complaint without converting the motion to dismiss into one for summary judgment. *Angstadt v. Midd-West Sch. Dist.*, 377 F.3d 338, 342 (3d Cir.2004) (citation omitted).²

² “The rationale underlying this exception is that the primary problem raised by considering documents outside the complaint—lack of notice to the plaintiff—is dissipated where the plaintiff has actual notice and has relied upon the documents in framing the complaint.” *Jones v. Intelli-Check, Inc.*, 274 F.Supp.2d 615, 625–26 (D.N.J.2003) (citations omitted).

The defendants, in moving to dismiss, in part, under Rule 12(b)(6), rely on materials beyond the allegations of the amended complaint, including, *inter alia*, (1) a certification from the defendants' counsel, Michael Young, Esq. (“Young Cert.”), with attached exhibits, (2) a certification from Magyar (“Magyar Cert.”), (3) a certification from Naeole (“Naeole Cert.”), with attached exhibits, (4) Donovan's curriculum vitae, (5) copies of Donovan's opinion and editorial articles for PPCNJ, (6) a copy of Holaday's 2001 W–2 Wage and Tax Statement, and (7) samples of Holaday's photos published in PPCNJ publications. (See 11–30–05 Young Cert. & Exs.; 11–9–05 Magyar Cert.; 11–8–05 Naeole Cert. & Exs.) The Court will not consider these additional documents submitted by the defendants because they constitute evidence outside the amended complaint, and are neither relied upon by the plaintiffs, nor integral to the amended complaint.³

³ The plaintiffs included certifications from Donovan and Holaday (with attached exhibits) with their opposition papers. The Court, for the reasons discussed *supra*, will not consider these certifications or any attached exhibits in resolving this motion.

II. Standard Of Review—Motion To Dismiss For Lack Of Subject Matter Jurisdiction

*3 A defendant may move to dismiss a complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) in one

of two ways. *Mortensen v. First Fed. Sav. & Loan Assoc.*, 549 F.2d 884, 891 (3d Cir.1977).⁴ First, a defendant may challenge subject matter jurisdiction by asserting that the complaint, on its face, does not allege sufficient grounds to establish subject matter jurisdiction (a “facial attack”). *Id.* The Court considers a facial attack under the same standard as a motion to dismiss under Rule 12(b)(6) and, as such, “assume[s] that the [well-pleaded] allegations contained in the complaint are true.” *Cardio-Med. Assocs. Ltd. v. Crozer-Chester Med. Ctr.*, 721 F.2d 68, 75 (3d Cir.1983). Also, the Court may dismiss the complaint in a facial attack “only if it appears to a certainty that the plaintiff will not be able to assert a colorable claim of subject matter jurisdiction.” *Iwanowa v. Ford Motor Co.*, 67 F.Supp.2d 424, 438 (D.N.J.1999) (citations omitted).

⁴ The defendants also move under Rule 12(h)(3), which provides that “[w]henever it appears by suggestion of the parties or otherwise that the court lacks jurisdiction of the subject matter, the court shall dismiss the action.” *Id.* “The distinction between a Rule 12(h)(3) motion and a Rule 12(b)(1) motion is simply that the former may be asserted at any time and need not be responsive to any pleading of the other party.” *Berkshire Fashions, Inc. v. M.V. Hakusan II*, 954 F.2d 874, 880 n. 3 (3d Cir.1992) (citation omitted). However, here “the motions are analytically identical because the only consideration is whether subject matter jurisdiction arises.” *Id.*

A defendant may also challenge subject matter jurisdiction by factually contesting the plaintiff’s allegations of the existence of subject matter jurisdiction (a “factual attack”). *Id.* (citation omitted). The Court, when considering a factual attack to subject matter jurisdiction, “may look beyond the pleadings and make its own determination as to whether it has the power to hear the action.” *Bricker v. Stouchburg Nursery & Garden Ctr.*, No. 03-6483, 2004 WL 1576652, at *1 (E.D.Pa. July 14, 2004) (citation omitted). “Thus, ‘no presumptive truthfulness attaches to plaintiff’s allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims.’” *Iwanowa*, 67 F.Supp.2d at 438 (citation omitted). Moreover, the Court “may consider affidavits, depositions and testimony to resolve factual issues bearing on jurisdiction.” *Id.* (citation omitted). Furthermore, the plaintiff bears the burden of proving that jurisdiction exists. *Mortensen*, 549 F.2d at 891.

A 12(b)(1) “factual evaluation may occur at any stage of the proceedings, from the time the answer has been served until after the trial has completed.” *Id.* (explaining that “[a] factual jurisdictional proceeding cannot occur until plaintiff’s allegations have been controverted”). Because the defendants have not filed an answer, the Court considers this motion a facial attack.⁵ Thus, the Court will only analyze the allegations in the complaint and will not consider the additional documents provided by the parties as described *supra* in resolving the motion.

⁵ The defendants also characterize their motion as a “facial attack.” (Defs. Br., at 5.)

III. Subject Matter Jurisdiction Under The FLSA

The defendants contend that the Court lacks subject matter jurisdiction over this action because the plaintiffs are exempt from coverage under the FLSA as bona fide executive, professional, or administrative employees. (Defs. Br., at 1.)⁶ The FLSA provides, in those industries within its scope, minimum labor standards by regulating, *inter alia*, wages, hours, and overtime compensation. Excluded from the FLSA’s scope is “any employee employed in a bona fide executive administrative, or professional capacity.” 29 U.S.C.

§ 213(a)(1).⁷ PPCNJ, as the employer, bears the burden of establishing that an exemption applies to its employees, and the exemptions are narrowly construed against the employer. *Corning Glass Works v. Brennan*, 417 U.S. 188, 196-97 (1974); *see Brock v. Claridge Hotel & Casino*, 846 F.2d 180, 183 (3d Cir.1988) (explaining that employer has “burden of proving the applicability of the [FLSA] exemption”).

⁶ The defendants argue for the first time in their reply brief that Donovan is an exempt independent contractor. (Defs. Reply Br., at 2.) The Court will not consider this contention because it is improper to raise arguments for the first time in reply papers. *Reap v. Cont'l Cas. Co.*, 199 F.R.D. 536, 550 n. 10 (D.N.J.2001).

⁷ “The FLSA does not define ‘executive, administrative, or professional capacity’; instead, it expressly delegates that task to the Secretary of Labor who may ‘from time to time’ alter the definitions.” *Kennedy v. Commw. Edison Co.*, 410 F.3d 365, 369 (7th Cir.2005) (citing 29 U.S.C. § 213(a)(1)).

A. FLSA Exemptions

1. Professional Employee Exemption

*4 The FLSA provides an exemption for any employee employed in a bona fide professional capacity. A bona fide professional employee is defined as any employee who is:

(1) Compensated on a salary or fee basis at a rate of not less than \$455 per week ..., exclusive of board, lodging, or other facilities; and

(2) Whose primary duty is the performance of work:

(i) Requiring knowledge of an advanced type in a field of science or learning customarily acquired by a prolonged course of specialized intellectual instruction; or

(ii) Requiring invention, imagination, originality or talent in a recognized field of artistic or creative endeavor.

29 C.F.R. § 541.300(a).⁸ The professional exemption is separated into two categories: (1) the “learned professional” exemption, and (2) the “creative professional” exemption. *Id.*

⁸ An employee is considered to be paid on a “salary basis” “if the employee regularly receives each pay period on a weekly, or less frequent basis, a predetermined amount constituting all or part of the employee's compensation, which amount is not subject to reduction because of variations in the quality or quantity of the work performed.” 29 C.F.R. § 541.602(a). On the other hand, an employee is paid on a “fee basis” “if the employee is paid an agreed sum for a single job regardless of the time required for its completion.” *Id.* at § 541.605(a).

An employee's “primary duty” is the “principal, main, major or most important duty that the employee performs.” *Id.* at § 541.700(a). The Court, in determining an employee's primary duty, considers “all [of] the facts in a particular case, with the major emphasis on the character of the employee's job as a whole.” *Id.* Further, the Court can consider, *inter alia*, the following factors: (1) “the relative importance of the exempt duties as compared with other types of duties”; (2) “the amount of time spent performing exempt work”; (3) “the employee's relative freedom from direct supervision”; and (4) “the relationship between the employee's salary and the wages paid to

other employees for the kind of nonexempt work performed by the employee.” *Id.* In determining whether exempt work is the primary duty of an employee,

the amount of time spent performing exempt work can be a useful guide.... Thus, employees who spend more than 50 percent of their time performing exempt work will generally satisfy the primary duty requirement. Time alone, however, is not the sole test, and ... exempt employees [need not] spend more than 50 percent of their time performing exempt work. Employees who do not spend more than 50 percent of their time performing exempt duties may nonetheless meet the primary duty requirement if the other factors support such a conclusion.

Id. at § 541.700(b).

a. The “learned professional” exemption

An employee's primary duty, to qualify for the learned professional exemption, must be “the performance of work requiring advanced knowledge in a field of science or learning customarily acquired by a prolonged course of specialized intellectual instruction.” *Id.* at § 541.301(a). Thus, PPCNJ must satisfy three elements to show that the plaintiffs are learned professionals: “(1) The employee must perform work requiring advanced knowledge; (2) The advanced knowledge must be in a field of science or learning; and (3) The advanced knowledge must be customarily acquired by a prolonged course of specialized intellectual instruction.” *Id.*

“[W]ork requiring advanced knowledge” constitutes work which

is predominantly intellectual in character, and which includes work requiring the consistent exercise of discretion and judgment, as distinguished from performance of routine mental, manual, mechanical or physical work. An employee who performs work requiring advanced knowledge generally uses the advanced knowledge to analyze, interpret or make deductions from varying facts or circumstances.

Advanced knowledge cannot be attained at the high school level.

Id. at § 541.301(b). Also, “field[s] of science or learning” include

the traditional professions of law, medicine, theology, accounting, actuarial computation, engineering, architecture, teaching, various types of physical, chemical and biological sciences, pharmacy and other similar occupations that have a recognized professional status as distinguished from the mechanical arts or skilled trades where in some instances the knowledge is of a fairly advanced type, but is not in a field of science or learning.

Id. at 541.301(c).

The phrase “customarily acquired by a prolonged course of specialized intellectual instruction” limits

the exemption to professions where specialized academic training is a standard prerequisite for entrance into the profession. The best *prima facie* evidence that an employee meets this requirement is possession of the appropriate academic degree. However, the word “customarily” means that the exemption is also available to employees in such professions who have substantially the same knowledge level and perform substantially the same work as the degreed employees, but who attained the advanced knowledge through a combination of work experience and intellectual instruction. Thus, for example, the ... exemption is available to the occasional lawyer who has not gone to law school, or the occasional

chemist who is not the possessor of a degree in chemistry. However, the ... exemption is not available for occupations that customarily may be performed with only the general knowledge acquired by an academic degree in any field, with knowledge acquired through an apprenticeship, or with training in the performance of routine mental, manual, mechanical or physical processes. The ... exemption also does not apply to occupations in which most employees have acquired their skill by experience rather than by advanced specialized intellectual instruction.

*5 *Id.* at § 541.301(d).

“The areas in which the [learned] professional exemption may be available are expanding.” *Id.* at § 541.301(f). “When an advanced specialized degree has become a standard requirement for a particular occupation, that occupation may have acquired the characteristics of a learned profession.” *Id.* Moreover, “[a]ccrediting and certifying organizations ... may develop ... specialized curriculums and certification programs which, if a standard requirement for a particular occupation, may [also] indicate that the occupation has acquired the characteristics of a learned profession.” *See id.* (listing examples).

b. The “creative professional” exemption

An employee's primary duty, to qualify for the creative professional exemption, must be “the performance of work requiring invention, imagination, originality or talent in a recognized field of artistic or creative endeavor as opposed to routine mental, manual, mechanical or physical work.” *Id.* at § 541.302(a). Also, the work performed must be “in a recognized field of artistic or creative endeavor ... such [as] music, writing, acting and the graphic arts.” *Id.* at § 541.302(b).⁹ Further,

⁹ However, this exemption “does not apply to work which can be produced by a person with general manual or intellectual ability and training.” *Id.* at § 541.302(a).

[t]he requirement of “invention, imagination, originality or talent” distinguishes the creative professions from work that primarily depends on intelligence, diligence and accuracy. The duties of employees vary widely, and exemption as a creative professional depends on the extent of the invention, imagination, originality or talent exercised by the employee. Determination of exempt creative professional status, therefore, must be made on a case-by-case basis. This requirement generally is met by actors, musicians, composers, conductors, and soloists; painters who at most are given the subject matter of their painting; cartoonists who are merely told the title or underlying concept of a cartoon and must rely on their own creative ability to express the concept; essayists, novelists, short-story writers and screen-play writers who choose their own subjects and hand in a finished piece of work to their employers (the majority of such persons are, of course, not employees but self-employed); and persons holding the more responsible writing positions in advertising agencies. This requirement generally is not met by a person who is employed as a copyist, as an “animator” of motion-picture cartoons, or as a retoucher of photographs, since such work is not properly described as creative in character.

Journalists may [also] satisfy the duties requirements for the creative professional exemption if their primary duty is work requiring invention, imagination, originality or talent, as opposed to work which depends primarily on intelligence, diligence and accuracy. Employees of newspapers, magazines, television and other media are not exempt creative professionals if they only collect, organize and record information that is routine or already public, or if they do not contribute a unique interpretation or analysis to a news product. Thus, for example, newspaper reporters who merely rewrite press releases or who write standard recounts of public information by gathering facts on routine community events are not exempt creative professionals. Reporters also do not qualify as exempt creative professionals if their work product is subject to substantial control by the employer. However, journalists may qualify as exempt creative professionals if their primary duty is performing on the air in radio, television or other electronic media; conducting investigative interviews; analyzing or interpreting public events; writing editorials, opinion columns or other commentary; or acting as a narrator or commentator.

*6 *Id.* at §§ 541.302(c) & (d).

2. Administrative Employee Exemption

The FLSA also exempts any employee employed in a bona fide administrative capacity. 29 U.S.C. § 213(a)(1). An employee is employed in an administrative capacity if (1) the employee is paid on a salary or fee basis of at least \$455 per week; (2) the employee's “primary duty” includes the performance of office work and non-manual work that is “directly related to management policies or general business operations of the employer or the employer's customers”; and (3) the employee's performance of his or her primary duties include work “requiring the exercise of discretion and independent judgment.” 29 C.F.R. § 541.200(a).

“To qualify for the administrative exemption, an employee's primary duty must be the performance of work directly related to the management or general business operations of the employer or the employer's customers.” *Id.* at § 541.201(a). Work “directly related to the management or general business operations” refers to work “assisting with the running or servicing of the business, as distinguished, for example, from working on a manufacturing production line or selling a product in a retail or service establishment.” *Id.* Moreover,

[w]ork directly related to management or general business operations includes, but is not limited to, work in functional areas such as tax; finance; accounting; budgeting; auditing; insurance; quality control; purchasing; procurement; advertising; marketing; research; safety and health; personnel management; human resources; employee benefits; labor relations; public relations; government relations; computer network, internet and database administration; legal and regulatory compliance; and similar activities. Some of these activities may be performed by employees who also would qualify for another exemption.

Id. at § 541.201(b).

An employee's primary duty, to meet the administrative exemption, must also "include the exercise of discretion and independent judgment with respect to matters of significance." *Id.* at § 541.202(a). The "exercise of discretion and independent judgment" "involves the comparison and the evaluation of possible courses of conduct, and acting or making a decision after the various possibilities have been considered." *Id.* "The term 'matters of significance' refers to the level of importance or consequence of the work performed." *Id.*

The Court must interpret the phrase "discretion and independent judgment" "in the light of all the facts involved in the particular employment situation in which the question arises." *Id.* at § 541.202(b). The Court, in conducting this analysis, considers, *inter alia*, the following factors:

[(1)] whether the employee has authority to formulate, affect, interpret, or implement management policies or operating practices;

[(2)] whether the employee carries out major assignments in conducting the operations of the business;

*7 [(3)] whether the employee performs work that affects business operations to a substantial degree, even if the employee's assignments are related to operation of a particular segment of the business;

[(4)] whether the employee has authority to commit the employer in matters that have significant financial impact;

[(5)] whether the employee has authority to waive or deviate from established policies and procedures without prior approval;

[(6)] whether the employee has authority to negotiate and bind the company on significant matters;

[(7)] whether the employee provides consultation or expert advice to management;

[(8)] whether the employee is involved in planning long- or short-term business objectives;

[(9)] whether the employee investigates and resolves matters of significance on behalf of management; and

[(10)] whether the employee represents the company in handling complaints, arbitrating disputes or resolving grievances.

Id.

If an employee exercises "discretion and independent judgment",

the employee has authority to make an independent choice, free from immediate direction or supervision. However, employees can exercise discretion and independent judgment even if their decisions or recommendations are reviewed at a higher level. Thus, the term "discretion and independent judgment" does not require that the decisions made by an employee have a finality that goes with unlimited authority and a complete absence of review. The decisions made as a result of the exercise of discretion and independent judgment may consist of recommendations for action rather than the actual taking of action. The fact that an employee's decision may be subject to review and that upon occasion the decisions are revised or reversed after review does not mean that the employee is not exercising discretion and independent judgment.... [Further, the] exercise of discretion and independent judgment must be more than the use of skill in applying well-established techniques, procedures or specific standards described in manuals or other sources.... The exercise of discretion and independent judgment also does not include clerical or secretarial work, recording or tabulating data, or performing other mechanical, repetitive, recurrent or routine work.

Id. at §§ 541.202(c) & (e).

B. Application of the Exemptions to the Plaintiffs

The complaint states that (1) Donovan's salary at PPCNJ was \$25,000 annually, and (2) Holaday's salary at PPCNJ was \$40,000 annually. Thus, examining only the allegations in the complaint, the plaintiffs' salaries appear to satisfy the salary and wage requirements of the professional and administrative exemptions.¹⁰ Concerning the plaintiffs' primary duties as employees of PPCNJ, Donovan served as the "Vice President of Policy and Research" and Holaday was the "Marketing Director". However, the mere fact that the plaintiffs' job titles seemingly imply management or supervisory positions at PPCNJ, is insufficient in itself to establish the plaintiffs' statuses as exempt employees. *See id.* at § 541.2 ("A job title alone is insufficient to establish the exempt status of an employee. The exempt or nonexempt status of any particular employee must be determined on the basis of whether the employee's salary and duties meet the requirements of the regulations in this part.")

¹⁰ At a salary of \$25,000, Donovan would earn approximately \$480 per week. Also, Holaday, at a salary of \$40,000, would earn approximately \$769 per week.

*8 The substantive allegations in the complaint regarding the plaintiffs' employment duties also do not support a finding that they were professional or administrative employees. As the determination whether the plaintiffs are exempt as professional or administrative employees is fact intensive and must be made on a case-by-case basis, a conclusion that the plaintiffs are exempt at this early stage of the litigation would be premature. Also, the defendants have not argued that the

allegations in the complaint demonstrate that the plaintiffs are exempt from FLSA coverage. Instead, the defendants rely on certifications and other documentation which the Court has already excluded from consideration. Therefore, because the allegations in the complaint do not establish that the plaintiffs¹¹ are exempt professional or administrative employees, the Court will deny the motion to dismiss under Rules 12(b)(1), 12(b)(6), and 12(h)(3).

¹¹ The defendants fail to address the claims concerning NJWHL and NJWPL.

CONCLUSION

The Court, for the reasons discussed herein, finds the defendants have not shown that the allegations in the complaint show that the plaintiffs are exempt from FLSA coverage as professional or administrative employees. Accordingly, the Court will deny the motion to dismiss under Rules 12(b)(1), 12(b)(6), and 12(h)(3). This ruling is without prejudice to the right of the defendants to move to dismiss under Rule 12(b)(1) at an appropriate time, if the defendants seek to assert a "factual" challenge to subject matter jurisdiction. The Court will issue an appropriate order.

All Citations

Not Reported in F.Supp.2d, 2006 WL 1373230, 11 Wage & Hour Cas.2d (BNA) 1135

TAB 16

2018 WL 4489677

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Marie DOPICO, for Plaintiff and the class of members defined herein, et al., Plaintiffs,
v.

IMS TRADING CORP., et al., Defendants.

Civil Action No. 3:14-cv-1874-BRM-DEA

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Signed 09/18/2018

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OPINION

BRIAN R. MARTINOTTI, United States District Judge

*1 Before this Court is Defendants IMS Trading Corporation a/k/a IMS Pet Industries¹ (collectively “Defendants”) Motion to Dismiss (ECF No. 70-1). Plaintiffs Marie Dopico, John Banks, Calvin Locke, and Carly Heron, for plaintiffs and the class of members (collectively “Plaintiffs”), oppose the Motion. (ECF No. 72.) Having reviewed the parties’ submissions filed in connection with the Motion and having declined to hold oral argument pursuant to **Federal Rule of Civil Procedure 78(b)**, for the reasons set forth below and for good cause having been shown, Defendants’ Motion to Dismiss is **DENIED in part** and **GRANTED in part**.

¹ IMS Pet Industries is improperly captioned as IMS Pet Industries, Inc.

I. BACKGROUND

A. Factual Background

Defendants are engaged in the “business of manufacturing, producing, marketing, distributing, advertising, and/or selling

dog treats, including the Chinese-made duck jerky dog treats at issue in this litigation.” (Compl. (ECF No. 68) ¶ 12.) Plaintiffs are purchasers of the duck jerky dog treats, who allege their dogs became ill after ingesting Defendants’ product. (See ECF No. 68.)

Defendants made several representations on the packaging of the dog treats they manufactured, including:

- A. No artificial colors;
- B. No artificial additives;
- C. No artificial fillers;
- D. No by-products;
- E. The ingredients were duck breast filets, vegetable glycerin, soy protein, isolate, salt;
- F. “Healthy and natural treats with only the finest ingredients.”
- G. “We guarantee our product 100%!”
- H. “Inspected and independently tested.”
- I. “A healthy natural treat for dogs.”

(*Id.* ¶ 17.) Defendants also made two representations regarding the treats on their website: (1) “That’s why we go to great lengths to maintain the quality and consistency of our products;” and (2) “Offer the best treats for your pet.” (*Id.* ¶ 18.)

Plaintiffs contend the representations found on the packaging were false. (*Id.* ¶ 20.) The FDA allegedly “issued warnings, as early as 2007 and as recently as November 18, 2011, about dog illnesses after consuming duck jerky dog treats, which were made in China.” (*Id.* ¶ 22.) However, Defendants’ packaging did not warn purchasers of the danger and side effects of the treats. (*Id.* ¶¶ 23, 30.) Plaintiffs also contend that prior to October 2013, Defendants had received complaints regarding their dog treats stating their product has caused dogs to become ill or die. (*Id.* ¶ 28.)

B. Procedural History

Plaintiff Dopico commenced this class action in the Superior Court of New Jersey, Law Division, Middlesex County in January 2014. (Ex. A. to ECF No. 1.) The matter was removed on March 20, 2014, and on April 17, 2014, Dopico

filed a First Amended Complaint alleging: (1) Count I, breach of express warranty under the Uniform Commercial Code (“UCC”); (2) Count II, breach of implied warranty under the UCC; (3) Count III, violation of the New Jersey Consumer Fraud Act (“NJCFA”); (4) Count, IV violation of the Magnuson-Moss Warranty Act (“MMWA”); (5) Count V, unjust enrichment; (6) Count VI, failure to warn (products liability); and (7) Count VII, defective design or manufacture (products liability). (ECF Nos. 1, 9.) On May 7, 2014, IMS moved to dismiss the Amended Complaint, and on April 20, 2015, Judge Peter G. Sheridan, U.S.D.N.J, who has since then assumed senior status. dismissed Counts II, III, and V with prejudice as being subsumed by the New Jersey Products Liability Act (“NJPLA”). (ECF No. 20.)

*2 On September 18, 2015, Dopico filed a Motion to Amend the First Amended Complaint, naming two additional class representatives, one a resident of New Jersey, Banks, and the other a resident of Arizona, Locke. (ECF No. 31.) The proposed Second Amended Complaint included claims applicable to the Arizona plaintiff. (*Id.*) On February 1, 2016, the Court granted Plaintiffs’ Motion to Amend, and on February 2, 2016, Plaintiffs filed their Second Amended Complaint. (ECF Nos. 34, 35.) On February 16, 2016, Defendants filed an Answer to the Second Amended Complaint. (ECF No. 37.)

On June 23, 2017, Plaintiffs filed another Motion to Amend the Second Amended Complaint. (ECF No. 52.) On June 28, 2017, Defendants requested an extension of time to file an opposition to Plaintiff’s Motion for Leave to file a Third Amended Complaint and “permission to file a dispositive motion with respect to all breach of warranty claims set forth in Plaintiffs’ Complaint.” (ECF No. 53.) On June 30, 2017, the Court considered Plaintiffs’ letter and granted all requests. (ECF No. 54.) On July 24, 2017, Defendants filed a Motion to Dismiss Plaintiffs Second Amended Complaint. (ECF No. 56.) On January 30, 2018, the Court granted Plaintiffs’ Motion to Amend the Second Amended Complaint and administratively terminated without prejudice Defendants’ Motion to Dismiss. (ECF No. 67.) Plaintiffs filed the Third Amended Complaint on January 30, 2018. (ECF No. 68.) On February 13, 2018, Defendants filed this Motion to Dismiss Counts I and IV of Plaintiffs’ Third Amended Complaint. (ECF No. 70.) Plaintiffs oppose the Motion. (ECF No. 72.)

II. LEGAL STANDARD

In deciding a motion to dismiss pursuant to [Federal Rule of Civil Procedure 12\(b\)\(6\)](#), a district court is “required to

accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff].” *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). “[A] complaint attacked by a ... motion to dismiss does not need detailed factual allegations.” *Bell Atl. v. Twombly*, 550 U.S. 544, 555 (2007). However, the Plaintiff’s “obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is “not bound to accept as true a legal conclusion couched as a factual allegation.” *Papasan*, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555.

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’ ” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). “A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged.” *Id.* This “plausibility standard” requires the complaint allege “more than a sheer possibility that a defendant has acted unlawfully,” but it “is not akin to a ‘probability requirement.’ ” *Id.* (quoting *Twombly*, 550 U.S. at 556). “Detailed factual allegations” are not required, but “more than an unadorned, the defendant-harmed-me accusation” must be pled; it must include “factual enhancements” and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citing *Twombly*, 550 U.S. at 555, 557).

*3 “Determining whether a complaint states a plausible claim for relief [is] ... a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 679. “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]’—‘that the pleader is entitled to relief.’ ” *Id.* at 679 (quoting [Fed. R. Civ. P. 8\(a\)\(2\)](#)).

While as a general rule, a court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to 12(b)(6), the Third Circuit has held “a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant under Rule 56].” *In re Rockefeller Ctr.*

Props. Sec. Litig., 184 F.3d at 287. Specifically, courts may consider any “document integral to or explicitly relied upon in the complaint.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426.

III. DECISION

A. Whether Defendants’ Motion is Procedurally Barred

Plaintiffs argue Defendants’ Motion to Dismiss is procedurally deficient because it seeks dismissal after Defendants have already filed their Answer to Count I and Count IV to both the First Amended Complaint and the Second Amended Complaint. (ECF No. 72 at 7.) Defendants contend the Court granted Defendants permission to file a Motion to Dismiss as to all warranty claims set forth in the Third Amended Complaint. (ECF No. 73 at 1-2.) Defendants are correct.

On February 2, 2016, Plaintiffs filed their Second Amended Complaint. (ECF No. 35.) On February 16, 2016, Defendants filed an Answer to the Second Amended Complaint. (ECF No. 37.) On June 23, 2017, Plaintiffs filed another Motion to Amend the Second Amended Complaint. (ECF No. 52.) On June 28, 2017, Defendants requested an extension of time to file an opposition to Plaintiff’s Motion for Leave to file a Third Amended Complaint and “permission to file a dispositive motion with respect to all breach of warranty claims set forth in Plaintiffs’ Complaint.” (ECF No. 53.) On June 30, 2017, the Court considered Defendants’ letter and granted its request to file a dispositive motion with respect to all warranty claims. (ECF No. 54.) Defendants are in compliance with the Order as their Motion only seeks to dismiss two warranty claims. Accordingly, Plaintiffs’ argument that Defendants’ Motion is procedurally barred is misguided.

B. Breach of Express Warranty (Count I)

Defendants argue Plaintiffs’ breach of express warranty claim is “unsustainable” because the “representations” identified in the Third Amended Complaint “do not amount to express warranties under New Jersey law.” (ECF No. 70-1 at 18.) Specifically, they contend the representations are “affirmation[s] merely of the value of the goods or [] statement[s] purporting to be merely the seller’s opinion or commendation of the goods.” (*Id.* at 19 (quoting *N.J. Stat. Ann. § 12A:2-313*)). Plaintiffs contend the Third Amended Complaint sets forth specific representations which constitute

warranties, including statements that the dog treats were “healthy,” “natural,” “guarantee[d],” “inspected,” “tested,” and contained “no artificial additives.” (ECF No. 72 at 11.) Plaintiffs allege these representations constitute “affirmations of fact rather than opinions or amorphous boasts regarding quality.” (*Id.* at 12.)

*4 New Jersey’s Statute Annotated § 12A:2-313, which is analogous to U.C.C. § 2-313, provides:

- (1) Express warranties by the seller are created as follows:
 - (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
 - (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description
 - (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.
- (2) It is not necessary to the creation of an express warranty that the seller use formal words such as “warrant” or “guarantee” or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller’s opinion or commendation of the goods does not create a warranty.

Pursuant to New Jersey law, a plaintiff must allege the following to state a claim for breach of express warranty: “(1) that Defendant made an affirmation, promise or description [of] the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description.” *Snyder v. Farnam Cos.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011) (internal citations omitted). “A statement can amount to a warranty, even if unintended to be such by the seller, if it could fairly be understood ... to constitute an affirmation or representation that the [product] possesse[s] a certain quality or capacity relating to future performance.” *Avram v. Samsung Elecs. Am., Inc.*, 11-6973, 2013 WL 3654090, at *8 (D.N.J. July 11, 2013) (citations omitted). However, affirmations “merely of the value of the goods or a statement purporting to be

merely the seller's opinion or commendation of the goods does not create a warranty." *Snyder*, 792 F. Supp. 2d at 721 (quoting N.J. Stat. Ann. § 12A:2-313(2)). Moreover, mere puffery is "not considered specific enough to create an express warranty." *Id.* "While the alleged warranties may later be found to be no more than 'puffery,' except in clear cases, this is normally a question of fact for the jury." *Id.* at 723; *see In re Toshiba Am. HD DVD Mktg. & Sales Practices Litig.*, No. 08-939, 2009 WL 2940081, at *16 (D.N.J. Sept. 10, 2009) (dismissing a breach of warranty claim based on Defendant's statement that HD DVD Players were for "Today, Tomorrow, and Beyond," since the statement is just "puffery").

Typically, "courts have noted that 'whether a given statement constitutes an express warranty is normally a question of fact for the jury.' " *Id.* (quoting *In re Ford Motor Co. E-350 Van Prods. Liab. Litig.*, No. 03-4558, 2008 WL 4126264, at *4 (D.N.J. Sept. 3, 2008)).

The Court finds Plaintiffs have adequately alleged a breach of express warranty claim as to labeling on the dog treats, but not as to the representations on the website. Here, Plaintiffs contend the following phrases on Defendants' duck jerky dog treats label constitute express warranties that formed the basis of the bargain between Plaintiffs and Defendants:

- *5 A. No artificial colors;
- B. No artificial additives;
- C. No artificial fillers;
- D. No by-products;
- E. The ingredients were duck breast filets, vegetable glycerin, soy protein, isolate, salt;
- F. "Healthy and natural treats with only the finest ingredients."
- G. "We guarantee our product 100%!"
- H. "Inspected and independently tested."
- I. "A healthy natural treat for dogs."

(ECF No. 68 ¶ 17.) They also allege Defendants made two express warranties on their website: (1) "That's why we go to great lengths to maintain the quality and consistency of our products" and (2) "Offer the best treats for your pet." (*Id.* ¶ 18.) Defendants only contest that the label on the dog treats did not make an "affirmation, promise or description [of]

the product." (ECF No. 70-1 at 180-21.) They contend that the above representations are either puffery or "affirmation[s] merely of the value of the goods or [] statement[s] purporting to be merely the seller's opinion or commendation of the goods." (ECF No. 70-1 at 19.) As such, the Court will only address this element.

When analyzing the packaging label as a whole "it could fairly be understood ... to constitute an affirmation or representation that the [product] possesse[s] a certain quality or capacity relating to future performance." *Avram*, 2013 WL 3654090, at *8. The phrase "We guarantee our product 100%" coupled with "Inspected and independently tested" could be "fairly" understood to mean the product was tested and contained: (1) "No artificial colors"; (2) "No artificial additives"; (3) "No artificial fillers"; (4) "No by-products"; and (5) that "the ingredients were duck breast filets, vegetable glycerin, soy protein, isolate, salt." *See Snyder*, 792 F. Supp. 2d at 722 (holding "Plaintiffs have pointed to specific affirmations or promises by Defendants regarding the safety of the use of their Products on pets, and therefore their breach of warranty claim survives a motion to dismiss"); *see also Elias v. Ungar's Food Prod., Inc.*, 252 F.R.D. 233, 240 (D.N.J. 2008) (finding packaging statements regarding fat and calories per serving created express warranties). "[W]hether a given statement constitutes an express warranty is normally a question of fact for the jury." *Stewart v. Smart Balance, Inc.*, No. 11-6174, 2012 WL 4168584, at *12 (D.N.J. June 26, 2012) (finding that "[t]he question of whether the labeling as a whole is misleading to an average consumer is a question of fact, and is not appropriate basis for dismissal at this time"). Accordingly, Defendants' Motion to Dismiss the breach of warranty claim as to the labeling of the dog treats is **DENIED**

However, the Court finds Defendants' website statements do not amount to express warranties. The website statements are more akin to puffery and "affirmation[s] merely of the value of the goods or [] statement[s] purporting to be merely the seller's opinion or commendation of the goods." N.J. Stat. Ann. § 12A:2-313. Courts have established that words such as "great" and "best" are mere puffery. *See Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 945 (3d Cir. 1993) (dismissing a claim based on Defendant's statement that its product provided "superior engine protection," since that statement is just "puffery"); *Wojcik v. Borough of Manville*, No. A-1627-08T3, 2010 WL 322893, at *3 (N.J. Super. Ct. App. Div. Jan. 29, 2010) (holding "[s]tatements that the helmet was 'top rated' and a 'top seller' are not express warranties but are statements of value or commendations" and "[s]tatements

that the helmet was ‘one of the best’ and ‘great’ are opinions, and therefore, not express warranties”). Both words were used in the phrases quoted from Defendants’ website. Accordingly, Defendants’ Motion to Dismiss Plaintiffs’ claim that Defendants’ website contains express warranties that were breached is **GRANTED**.

C. MMWA (Count IV)

*6 Defendants argue “this case is utterly bereft of any legal or factual foundation” of MMWA warranty claims for three reasons: (1) the MMWA is inapplicable to written warranties that are governed by federal law; (2) the warranty claims are mere product descriptions and do not constitute written warranties under the MMWA; and (3) any MMWA implied warranty claims cannot be maintained by any of the New Jersey Plaintiffs because they are linked to a state law implied warranty claim that has already been dismissed by this Court. (See ECF No. 70-1 at 6-17.) Plaintiffs contend the warranty claims at issue are adequately plead and not governed by federal law, and if they are governed by federal law, they should be determined on summary judgment. (ECF No. 72 at 16-22.)

The MMWA provides that “a consumer who is damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief.” 15 U.S.C. § 2310(d)(1). However, the MMWA is “inapplicable to any written warranty the making or content of which is otherwise governed by Federal law. If only a portion of a written warranty is so governed by Federal law, the remaining portion shall be subject to this chapter.” 15 U.S.C. 2311(d).

In this case, the Federal Food, Drug, and Cosmetic Act (“FDCA”) and Food and Drug Administration (“FDA”) governs the Chinese-made duck jerky dog treats labeling on Defendants’ product. In 1938, Congress passed the FDCA, which gives the FDA power to ensure “foods are safe, wholesome, sanitary, and properly labeled.” 21 U.S.C. § 393(b)(2)(A); *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 251 (3d Cir. 2008) (“The FDCA grants the FDA authority to regulate the field of food safety.”). The FDCA defines “food” as “articles used for food or drink for man or other animals.” 21 U.S.C.A. § 321. Indeed, the Code of Federal Regulations contains a subsection dedicated to “Animal Food Labeling.” 21 C.F.R. § 501.1, *et seq.* This subsection is compromised of numerous FDA regulations governing the packaging of animal food,

including regulations such as: (1) the display panel of package form animal food (§ 501.1); (2) information panel of package for animal food (§ 501.2); (3) identity labeling of animal food in package form (§ 501.3); (4) designation of ingredients (§ 501.4); (5) name and place of business of manufacturer, packer, or distributor (§ 501.5); (6) labeling of animal food with number of servings (§ 501.6); (7) prominence of required statements (§ 501.8); (8) labeling warning statements (§ 501.17); and (9) misbranding of animal food (§ 501.18).

In addition, the FDA has explicitly stated on its public governmental website that it “regulates that can of cat food, bag of dog food, or box of dog treats or snacks in your pantry”. U.S. Food & Drug Administration, Pet Food, <https://www.fda.gov/animalveterinary/products/animalfoodfeeds/petfood/default.htm>. The FFDCA “requires that all animal foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled.” *Id.*

Lastly, Plaintiffs’ Third Amended Complaint acknowledges the FDA regulates dog treats. (See ECF No. 68 ¶ 22) (“The FDA had issued warning, as early as 2007 and as recently as November 18, 2011, about dog illnesses after consuming duck jerky dog treats, which were made in China.”). As such, the MMWA is inapplicable to any alleged express or implied warranty claims on the labeling of the dog treats. See *Stewart*, 2012 WL 4168584, at *14 (finding “[t]o the extent that ‘fat free’ is the equivalent of ‘defect free,’ despite the fact that compliant milk may contain no less than 0.5 grams of fat, the making or content of the claim is governed by Federal law”); *Reid v. GMC Skin Care USA Inc.*, No. 15-277, 2016 WL 403497, at *13 (N.D.N.Y. Jan. 15, 2016) (“The majority of courts that have considered whether § 2311(d) bars an MMWA claim founded on the labels of products governed by the FDCA have concluded that MMWA claim is barred.”); *Jasper v. MusclePharm Corp.*, No. 14-02881, 2015 WL 2375945, at *5-6 (D. Colo. April 9, 2015) (finding that because dietary supplement product labels containing allegedly misleading claims about the supplement’s attributes or effects were governed by the FDCA, § 2311(d) barred the plaintiff’s MMWA claim), *recommendation adopted*, 2015 WL 2375945 (D. Colo. May 15, 2015).² Defendants’ Motion to Dismiss Count IV of Plaintiffs’ Third Amended Complaint pertaining to the labeling of the dog treats is **GRANTED**.

² While many courts have dismissed MMWA claims on a motion to dismiss, the Southern District of California has denied a defendant’s motion to

dismiss, explaining that the issue of “[w]hether § 2311(d) precludes Plaintiff’s MMWA claim is better suited for a motion for summary judgment, when the record is more fully developed and the parties further analyze the statutory scheme under the facts of the case.” *Kanfer v. Pharmacare US, Inc.*, No. 15-0120, 2015 WL 6742201, at *10 (S.D. Cal. Nov. 4, 2015). This Court will follow the with the majority and *Stewart*, a previous New Jersey District Court case.

*7 Plaintiffs argue Defendants website warranty claims are unaffected by 15 U.S.C. 2311(d) because websites are not regulated by the FDA or FDCA. (ECF No. 72 at 22.) This argument is immaterial. “Claims under the MMWA depend upon the disposition of the underlying state law warranty claims.” *Argabright v. Rheem Mfg. Co.*, 201 F. Supp. 3d 578, 600 (D.N.J. 2016); *see Johansson v. Cent. Garden & Pet Co.*, 804 F. Supp. 2d 257, 265 (D.N.J. 2011) (“A claim under the MMWA relies on the underlying state law claim.”) Therefore, “if there exists no actionable warranty claim, there can be no violation of the MMWA.” *Argabright v. Rheem Mfg. Co.*, 201 F. Supp. 3d at 600; *In re: Ford Motor Co. Ignition Switch Prods. Liability Litig.*, No. 96-1814, 2001 WL 1266317, at *24 (D.N.J. Sept. 30, 1997) (dismissing MMWA claims against defendant because all express and implied warranty claims against defendant had been dismissed). The Court has dismissed Plaintiffs’ New Jersey state law express warranty claim above as to the website. Therefore, Defendants’ Motion to Dismiss Plaintiffs’ MMWA express warranty claim is also **DISMISSED** as to that claim. Plaintiffs’ implied warranty claim pertaining to the website is also **DISMISSED** as to the New Jersey Plaintiffs because they are inextricably linked to state law

implied warranty claims that have already been dismissed by this Court.³ All implied warranty claims as to out-of-state residents will proceed. Accordingly, Defendants’ Motion to Dismiss Count IV of the Third Amended Complaint is **GRANTED** as to all express warranties. It is also **GRANTED** as to New Jersey Plaintiffs’ implied warranty claims.

³ Defendants’ Motion to Dismiss only seeks to dismiss Plaintiffs’ implied warranty claims under the MMWA as to all New Jersey Plaintiffs. (ECF No. 70-1 at 16.) Plaintiffs concede Judge Sheridan dismissed these claims, but argue the claims are not precluded as to non-New Jersey Plaintiffs.

IV. CONCLUSION

For the reasons set forth above, Defendants’ Motion to Dismiss is **GRANTED in part** and **DENIED in part**. Defendants’ Motion to Dismiss the breach of warranty claim (Count I) as to the labeling of the dog treats is **DENIED** but **GRANTED** as to Plaintiffs’ claim that Defendants’ website contains express warranties that were breached. Defendants’ Motion to Dismiss the MMWA claim (Count IV) as it pertains to the labeling of the dog treats is **GRANTED**. Plaintiffs’ implied warranty MMWA claim pertaining to the website is only **DISMISSED** as to the New Jersey Plaintiffs. All implied warranty claims as to out-of-state residents will proceed.

All Citations

Not Reported in Fed. Supp., 2018 WL 4489677, 96 UCC Rep.Serv.2d 960

TAB 17

2014 WL 3056026

 KeyCite Yellow Flag - Negative Treatment
Distinguished by [Beavers-Gabriel v. Medtronic, Inc.](#), D.Hawai'i, January 9, 2015

2014 WL 3056026

Only the Westlaw citation is currently available.

United States District Court,
C.D. California.

Kabina DUNBAR, et al

v.

MEDTRONIC, INC., et al.

No. CV 14-01529-RGK (AJWx).

|

Signed June 25, 2014.

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Proceedings: (IN CHAMBERS) Order re: Defendants' Motion to Dismiss (DE 32)

[R. GARY KLAUSNER](#), District Judge.

*1 Sharon L. Williams (Not Present) Deputy Clerk

I. INTRODUCTION

On January 30, 2014, Kabina Dunbar and 28 other individuals ("Plaintiffs") filed a state court action against Medtronic, Inc., Medtronic Sofamor Danek USA, Inc., and Medtronic Vertelink, Inc. (collectively, "Medtronic"). The action arises from alleged injuries caused by a medical product manufactured and sold by Medtronic. Plaintiffs allege the following eight claims: (1) Fraudulent Misrepresentation and Fraud in the Inducement; (2) Strict Products Liability—Failure to Warn; (3) Strict Products Liability—Design Defect; (4) Strict Products Liability—Misrepresentation; (5) Products Liability—Negligence; (6) Negligence Per Se; (7) Breach of Express Warranty; and (8) Loss of Consortium.

On February 28, 2014, Medtronic removed the action to federal court on the ground of diversity jurisdiction. On March 7, 2014, Medtronic filed the current Motion to Dismiss. For the following reasons, the Court **grants in part** Medtronic's motion.

II. FACTUAL BACKGROUND

Medtronic is the manufacturer and seller of the INFUSE Bone Graft and LT-Cage (collectively known as "INFUSE"), a prescription medical device used in spinal fusion surgeries. The purpose of the device is to accomplish the same outcome as implanting a patient's own bone or cadaver bone between the vertebrae in the spine, obviating the need for bone harvesting. The two components of the device are (1) a metallic cylindrical cage (LT-Cage), and (2) a liquid protein and collagen sponge carrier for the protein (INFUSE Bone Graft), both of which are placed inside the cage. The LT-Cage maintains the spacing between the vertebrae and temporarily stabilizes the diseased region of the spine, and the liquid protein binds with the sponge to stimulate bone growth.

INFUSE is a Class III device under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"). Class III is a classification reserved for devices that pose the greatest risk of death or complications. For this reason, Medtronic was required to obtain pre-market approval ("PMA") from the FDA before it could sell or distribute INFUSE.

In 2001, Medtronic filed a PMA application, and in 2002, the FDA granted approval for use of INFUSE to treat **degenerative disc disease**. In its approval letter, the FDA stated that INFUSE may only be implanted (1) from the anterior (front) abdomen, and (2) placed within lumbar spine levels L4 through S1. Additionally, the FDA approved label states that the INFUSE **bone graft** must be used within the LT-Cage. Therefore, any variation of its use (e.g., posterior implant or use without the LT-Cage) constitutes "off-label" use of the device.

According to the Complaint, each of the plaintiffs underwent spinal surgery using the off-label INFUSE. Specifically, the plaintiffs' surgeries either did not conform with the method of implant approved by the FDA and/or did not conform with the labeling specifications. Each of the plaintiffs have suffered post-operative injury in the form of severe pain as a result of uncontrolled bone growth. Plaintiffs allege that Medtronic actively promoted the off-label use of INFUSE, failed to warn about the risks of off-label use, failed to report adverse events,

2014 WL 3056026

and misrepresented material health and safety product risk information. According to Plaintiffs, had the risks associated with off-label INFUSE been known, they would not have undergone that particular course of treatment, which allegedly resulted in their injuries.

III. JUDICIAL STANDARD

***2** The federal pleading standard states in relevant part that “a claim for relief must contain … a short and plain statement of the claim showing that the pleader is entitled to relief.” [Fed.R.Civ.P. 8\(a\)\(2\)](#). Under [Rule 12\(b\)\(6\) of the Federal Rules of Civil Procedure](#), a party may move to dismiss for failure to state a claim upon which relief can be granted. In deciding a [Rule 12\(b\) \(6\)](#) motion, the court must assume allegations in the challenged complaint are true, and construe the complaint in the light most favorable to the non-moving party. [Cahill v. Liberty Mut. Ins. Co.](#)., 80 F.3d 336, 337–38 (9th Cir.1996). However, a court need not accept as true unreasonable inferences, unwarranted deductions of fact, or conclusory legal allegations cast in the form of factual allegations. *See W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir.1981). Furthermore, a pleading must contain sufficient factual matter that, if accepted as true, states a claim that is plausible on its face. [Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 \(2009\). A claim is facially plausible when there are sufficient factual allegations to draw a reasonable inference that the defendant is liable for the misconduct alleged. *Id.*](#)

IV. DISCUSSION

Medtronic seeks dismissal on the ground that the FDCA and MDA expressly or impliedly preempt all of Plaintiffs' claims. Medtronic also challenges Plaintiffs' claims on grounds independent of the preemption argument. The Court agrees in part with Medtronic's arguments as follows.

A. Federal Preemption Pursuant to the FDCA and MDA

1. Express Preemption Under § 360k(a)

§ 360k(a) of the MDA provides for express preemption, and states in pertinent part:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

[21 U.S.C. § 360k\(a\).](#)

The U.S. Supreme Court has set forth a two-step analysis for courts to determine whether the MDA expressly preempts a state law claim within the meaning of [§ 360k\(a\)](#). First, a court must determine whether the FDA has established requirements applicable to the particular medical device at issue. [Reigel v. Medtronic, Inc.](#), 552 U.S. 312, 321, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008). If the first step is answered in the affirmative, the court must proceed to the second step. The second step requires a court to determine whether the state law claims are based on state requirements that are different from, or in addition to, the federal requirements.¹ *Id.* at 321–322. “State requirements” include a state's common law legal duties. [Reigel](#), 552 U.S. at 324–25. If the state requirements stemming from the claim differ from, or add to, the federal requirements, the state claim is expressly preempted by operation of [§ 360k\(a\)](#). However, state claims that are premised on a violation of FDA regulations escape express preemption, as they are considered “parallel,” rather than different from, or in addition to, the federal requirements. *Id.*

¹ As stated in the statute, the court must also determine whether the state requirements relate to the safety and effectiveness of the device. Here, there is no dispute that the state requirements asserted by Plaintiffs relate to the safety and effectiveness of the INFUSE.

***3** Even if a state claim runs parallel to federal requirements and escapes express preemption, it may still be subject to implied preemption under § 337(a) and [Buckman Co. v. Plaintiffs' Legal Comm.](#), 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001).

2. Implied Preemption Under § 337(a) and Buckman

§ 337(a) of the MDA provides that all actions to enforce FDA requirements “shall be by and in the name of the United States.” [21 U.S.C. § 337\(a\)](#). In [Buckman Co. v. Plaintiffs' Legal Comm.](#), the U.S. Supreme Court interpreted this

2014 WL 3056026

provision to mean that even state claims that run parallel to federal requirements are preempted unless they are grounded in traditional state tort law, and do not depend exclusively on a federal requirement. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). As pointed out by other courts, this does not mean that a plaintiff can never bring a state law claim based on conduct that violates the FDCA. In fact, the conduct that gives rise to the claim *must* violate the FDCA to escape express preemption. Instead, to avoid implied preemption, the conduct giving rise to the state claim must also be the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted. See *Houston v. Medtronic, Inc.*, 957 F.Supp.2d 1166, 1175 (C.D.Cal.2013).

B. Plaintiffs' Claims

Medtronic argues at the outset that the MDA expressly preempts all of Plaintiffs' claims. As stated above, determination of express preemption involves a two-step process. First, a court determines whether the FDA has established requirements applicable to the device at issue. If the court determines that requirements on the device have been established, the court must then determine whether the state claims are based on requirements different from, or in addition to, the federal requirements. The Court begins its analysis of Plaintiffs' claims by addressing step one—whether the FDA has established requirements—since this issue is device-specific (as opposed to claim-specific), and the Court's determination of this issue applies to all claims asserted by Plaintiffs.

Riegel v. Medtronic involved a Class III catheter that had received premarket approval. 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008). The U.S. Supreme Court in *Riegel* noted that, unlike general labeling duties, premarket approval is specific to individual devices. *Riegel*, 552 U.S. at 323. The Court further stated that, with respect to such devices, the FDA allows almost no deviation from the specifications contained in the approved applications, as adherence to the specifications allows reasonable assurance of safety and effectiveness. *Id.* Based on this, the Court reasoned that obtaining premarket approval for the catheter was akin to the establishment of federal requirements on the device. *Id.*

Similarly, INFUSE is also a Class III device that obtained premarket approval. It was subject to the same rigorous review process and post-approval manufacturing requirements. Therefore, the Court finds that the first

prong of the *Riegel* test—whether the FDA has established requirements for the device—has been met.

*4 Having made the above finding with respect to the INFUSE device, the Court will determine step two of the express preemption analysis and other the claim-specific issues, addressing each claim in turn.

1. Strict Products Liability—Failure to Warn

Plaintiffs allege that Medtronic knew of the dangers relating to off-label use of INFUSE, and had a duty to warn Plaintiffs and their physicians of these dangers. (Compl., ¶¶ 358–361.) Nonetheless, Medtronic failed to provide adequate warning, even though the off-label use was reasonably foreseeable and the dangers from such use were not readily recognizable to an ordinary consumer or physician. (Compl., ¶¶ 362–365.)

By way of their allegations, Plaintiffs base their claim on a theory that either (1) Medtronic was required to include warnings beyond those in the FDA-approved label of INFUSE, or (2) Medtronic was obligated to issue post-sale warnings about potential adverse effects from off-label use of INFUSE. As to post-sale warnings, while the FDA permits such warnings, it does not require them. See *Stengel*, 704 F.3d at 1234. In either case, Plaintiffs' claim seeks to impose on Medtronic labeling or warning requirements that go beyond what federal law requires. As there is no dispute that the issue of labeling and warning relate to the safety and effectiveness of the device, this claim is expressly preempted by the MDA.

Plaintiffs' Strict Products Liability—Failure of Warn claim is dismissed.

2. Strict Products Liability—Design Defect

This claim alleges that INFUSE was defectively designed because it was unsafe when used in the manner that was either promoted by Medtronic or reasonably foreseen by Medtronic. (Compl., ¶ 378.) Plaintiffs further allege that the device was defectively designed because the risks of danger outweigh its benefits. (Compl., ¶ 379.)

By way of their claim, Plaintiffs attack the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. To prevail on this claim, a jury would have to make findings that conflict with those of the FDA. Circuit courts have found that such claims are expressly preempted by § 360k. See *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1206 (8th Cir.2010); *Mitchell v. Collagen Corp.*, 126 F.3d

2014 WL 3056026

902, 913–14 (7th Cir.1997), *cert. denied*, 523 U.S. 1020, 118 S.Ct. 1300, 140 L.Ed.2d 467 (1998) (holding that strict liability claim that product was “unreasonably dangerous” was expressly preempted because it conflicted with FDA premarket approval of the product).

Plaintiffs' Strict Products Liability—Design Defect claim is dismissed.

3. Products Liability—Negligence

Plaintiffs allege that Medtronic breached its duties to Plaintiffs by performing the following acts or omissions: (1) improper promotion and marketing of INFUSE for off-label use; (2) failure to warn Plaintiffs and physicians of the dangers associated with off-label INFUSE; (3) failure to exercise reasonable care in complying with federal law and regulations applicable to the sale and marketing of INFUSE; and (4) failure to exercise reasonable care in preventing INFUSE from creating an unreasonable risk of harm to Plaintiffs when used in a reasonably foreseeable manner. (Compl., ¶ 407.)

*5 As to the first alleged act of negligence, the Court finds the claim not expressly preempted, but rather, impliedly preempted. In *Carson v. Depuy Spine, Inc.*, the Ninth Circuit considered whether off-label promotion by a drug manufacturer is prohibited by the FDCA, and determined that it is. *See Carson*, 365 Fed.Appx. 812, 815 (9th Cir.2010) (unpublished) (“[T]he marketing and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA.”). Although *Carson* is not binding, this Court finds the Ninth Circuit’s reasoning persuasive and follows its holding. As such, Plaintiffs’ claim based on off-label promotion runs parallel to the FDCA and survives express preemption. However, there is no claim for illegal off-label promotion rooted in traditional state tort law. Therefore, any common law claim arising from such an action exists only by virtue of the FDCA. Permitting this claim to proceed would essentially allow a private litigant to attempt enforcement of the FDCA. *Buckman* bars such an action under § 337(a). Therefore, Plaintiffs’ negligence claim based on off-label promotion is impliedly preempted.

As to Plaintiffs’ negligence claim based on a failure to warn or dangerous design (2 and 4), the claim is expressly preempted for the same reasons stated in the preceding sections, IV.B. 1. and 2. Specifically, the claim fails because it is premised on the theory that state law required Medtronic to warn about the risks of off-label use, or make cost-benefit decisions about the design. These requirements are different from, or in addition

to, those imposed by the federal requirements. Therefore, Plaintiffs’ claim based on failure to warn and dangerous design is expressly preempted

Finally, to the extent Plaintiffs base their claim on failing to comply with other federal laws or regulations applicable to the sale or marketing of INFUSE, Plaintiffs fail to allege sufficient facts. Specifically, Plaintiffs fail to allege facts substantiating a violation of any particular federal requirement applicable to the device. Therefore, the Court cannot reasonably infer that these other “federal law of regulations” run parallel to the FDCA. Nor can the Court determine whether the claim can exist independently from the FDCA. Plaintiffs’ conclusory allegation that Medtronic failed to comply with federal law and regulations is insufficient to overcome either express or implied preemption.

Plaintiffs’ Products Liability—Negligence claim is dismissed.

4. Negligence Per Se

Under the theory of negligence per se, as long as other requirements are met,² a presumption of negligence arises from the violation of a statute. *Padilla v. Pomona College*, 166 Cal.App.4th 661, 675, 82 Cal.Rptr.3d 869 (2008).

² The other requirements are: the statute at issue must have been enacted to protect a class of persons, of which the plaintiff is a member, against the type of harm the plaintiff suffered as a result of the statutory violation. *Padilla v. Pomona College*, 166 Cal.App.4th 661, 675, 82 Cal.Rptr.3d 869 (2008).

Here, Plaintiffs’ claim for negligence per se is “based on [Medtronic’s] violations of FDCA regulations.”³ (Compl. ¶ 417.) As such, the standard of care for this negligence claim relies exclusively on the FDCA, and adjudication of this claim relies on the existence of the federal requirements. While courts have generally allowed a negligence per se claim based on violation of a federal statute, the plain language of § 337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails.

³ Plaintiffs specifically refer to regulations involving, among other things, compliance with PMA approval standard orders, promotion of devices for off-label uses, approval by the FDA for any product changes, and reporting adverse events. (Compl., ¶ 418.)

2014 WL 3056026

*6 § 337(a) expressly states that all actions to enforce FDA requirements “shall be by and in the name of the United States.” 21 U.S.C. § 337(a). As *Buckman* concluded, this provision “leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.” *Buckman*, 531 U.S. at 349 n.4. Allowing a litigant to assert a negligence per se claim based on violation of the FDCA would frustrate congressional intent regarding the regulation of medical devices, and interfere “with the federal statutory scheme, which ‘amply empowers the FDA to punish and deter fraud against the Administration.’ ” *Id.* at 348. Stated differently, a negligence per se claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages. Since the latter is not available as a result of § 337(a), the Court finds that the former is preempted as well.

Plaintiffs' Negligence Per Se claim is dismissed.

5. Fraud Claims: Fraudulent Misrepresentation, Fraud in the Inducement and Strict Products Liability—Misrepresentation

Plaintiffs' claim for Fraudulent Misrepresentation and Fraud in the Inducement alleges that Medtronic “fraudulently and intentionally misrepresented material and important health and safety product risk information from Plaintiff and Plaintiff's physicians.” (Compl., ¶ 343.) Specifically, Plaintiffs allege that Medtronic fraudulently concealed and misrepresented (1) the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label use of INFUSE; (2) the practice of promoting and marketing to physicians the off-label practice of using INFUSE without an LT-Cage and placing it posteriorly or laterally; and (3) information about the known comparative risks and benefits of the use of INFUSE, and the relative benefits and availability of alternate products, treatments and/or therapies. (Compl., ¶ 345.)

Similarly, Plaintiffs' claim for Strict Products Liability—Misrepresentation alleges that in the course of marketing INFUSE, Medtronic made untrue representations of material facts and omitted material information to Plaintiffs, Plaintiffs' physicians, and the public at large. (Compl., ¶ 388.) Plaintiffs further allege that Medtronic sponsored biased medical trials, reports, and articles that wrongfully and inaccurately claim that the dangers inherent to off-label use of INFUSE did not exist, or were significantly less than the actual dangers. *Id.* Finally, Plaintiffs allege that Plaintiffs and their

physicians would not have proceeded with the off-label use of INFUSE had they known the material facts that Medtronic misrepresented or omitted. *Id.*

As to the issue of preemption, federal law that prohibits promotion of off-label uses of approved devices certainly prohibits *false or misleading* promotion. As such, Plaintiffs' fraud claims are not expressly preempted, because they run parallel to requirements and prohibitions imposed by the FDCA. Additionally, Plaintiffs' claims also escape implied preemption under § 337(a) and *Buckman* because claims of fraud are moored in traditional state common law and exist independently from the FDCA. Therefore, Plaintiffs' fraud claims are not preempted.

*7 Because these claims sound in fraud, Federal Rule of Civil Procedure (“Rule”) 9(b) applies. Under Rule 9(b), a plaintiff who asserts a fraud claim must plead the specific circumstances surrounding the alleged fraud. Here, Plaintiffs allege separate paragraphs for each of the named plaintiffs who underwent *bone graft* surgery. For each plaintiff, Plaintiffs uniformly allege “representatives of Medtronic ... intentionally and/or carelessly, informed plaintiff's surgeon of the safety and efficacy of [INFUSE] as applied to [that] procedure.” (Compl., ¶¶ 269–324.) Plaintiffs also allege a series of allegations involving Medtronic's off-label promotion. Such allegations primarily involve general statements that Medtronic manipulated medical literature and paid opinion leader consultants to misrepresent the safety and efficacy of INFUSE's off-label use. These boilerplate and general allegations fail to meet the heightened pleading requirements, as they fail to allege “the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation.” *Alan Neuman Prods., Inc. v. Albright*, 862 F.2d 1388, 1392–93 (9th Cir.1988).

However, Plaintiffs also allege that Dr. Burkus and Dr. Haid received large sums of money from Medtronic to create fraudulent research. (Compl., ¶¶ 132–134.) Such research led to publications and presentations that promoted the use of off-label INFUSE, one of which was a 2004 article published in *The Spine Journal*. *Id.* These publications and presentations allegedly concealed the risk and danger of the off-label INFUSE. (Compl., ¶ 133.) Plaintiffs allege that prior to the surgeries, Plaintiffs' surgeons “believe that he/she read articles by Drs. Burkus and Haid endorsing the use of [INFUSE] as safe and effective, while failing to warn of the true risks of bone overgrowth and inflammatory

reactions.” (Compl., ¶ 327.) The Court finds that these allegations provide sufficient factual basis that meet the heightened pleading requirements of Rule 9(b).

Plaintiffs' claims for Fraudulent Misrepresentation/Fraud in the Inducement and Strict Products Liability—Misrepresentation are not preempted and adequately state a claim for relief.

6. Breach of Express Warranty

Plaintiffs allege that Medtronic “utilized journal articles, advertising media, sales representatives/consultants and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of [INFUSE] and expressly warranted to physicians and other members of the general public and medical community that such off-label uses ... were safe and effective.” (Compl., ¶ 427.) Plaintiffs further allege that their treating surgeon relied on Medtronic's express warranties regarding the safety and efficacy of off-label use of INFUSE, but such uses, in fact, were not effective, safe and proper for the uses as warranted. (Compl., ¶ 429.)

As an initial matter, the Court finds that this claim is neither expressly or impliedly preempted. As discussed in the preceding section, federal law prohibits false or misleading off-label promotion. To the extent Plaintiffs base their claim on Medtronic's alleged misleading warranties of off-label INFUSE, Plaintiff does not seek to impose any requirement different from, or additional to, existing federal requirements. Nor is the claim preempted under § 337(a) and *Buckman*, as a claim for breach of express warranty originates from traditional state law that predates, and exists independently from, the FDCA.

*8 However, under California law, a breach of express warranty requires that (1) the seller made an affirmation of fact or promise, or provided a description of its goods; (2) the promise or description formed the basis of the bargain; (3) the seller breached the express warranty; and (4) the breach caused injury to the plaintiff. *Cal. Comm.Code* § 2313(1)(a);

Williams v. Beechnut Nutrition Corp., 185 Cal.App.3d 135, 142, 229 Cal.Rptr. 605 (1986). Here, Plaintiffs have alleged no facts demonstrating that Medtronic made any affirmations specifically to Plaintiffs or their surgeons, so as to form the basis of the bargain.

Moreover, to adequately state a claim for breach of express warranty, a plaintiff must plead that notice of the alleged breach was provided to the seller within a reasonable time after discovery of the breach. *Alvarez v. Chevron Corp.*, 656 F.3d 926, 932 (9th Cir.2011) (internal citations omitted). Here, Plaintiffs make no such allegation. Therefore, Plaintiffs' claim fails for this additional reason.

Plaintiffs' claim for Breach of Express Warranty is dismissed.

7. Loss of Consortium

As pointed out by Medtronic, Plaintiffs' loss of consortium claim alleges injuries suffered by Plaintiffs' spouses. However, none of the plaintiffs are named as spouses of an individual allegedly injured by INFUSE, nor does any plaintiff claim to be married. Plaintiffs fail to raise any argument in response to Medtronic's challenge to this claim.

Plaintiffs' claim for Loss of Consortium is dismissed.

V. CONCLUSION

Based on the foregoing reasons, the Court **grants in part** Medtronic's Motion to Dismiss. Specifically, the Court dismisses all claims except for Plaintiffs' claims for (1) Fraudulent Misrepresentation and Fraudulent Inducement; and (2) Strict Products Liability—Misrepresentation.

IT IS SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2014 WL 3056026

TAB 18

2013 WL 1845615

2013 WL 1845615

Only the Westlaw citation is currently available.
United States District Court, D. New Jersey.

Stanley FISHMAN, Suzanne Bowsver, and Vicki Plunkett, individually and on behalf of all others similarly situated, Plaintiffs,

v.

GENERAL ELECTRIC COMPANY, Defendant.

Civ. No. 2:12-cv-00585 (WJM).

|

April 30, 2013.

Attorneys and Law Firms

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Charles J. Falletta, Herve Gouraige, Jeffrey J. Greenbaum, Sills Cummis & Gross P.C., Newark, NJ, for Defendant.

OPINION

WILLIAM J. MARTINI, District Judge.

*1 Plaintiffs Stanley Fishman, Suzanne Bowser,¹ and Vicki Plunkett filed this putative class action against Defendant General Electric Company (“GE”). This matter comes before the Court on Defendant’s motion to dismiss under **Federal Rule of Civil Procedure 12(b)(6)**. There was no oral argument. **Fed.R.Civ.P. 78(b)**. For the reasons set forth below, Defendant’s motion to dismiss is **GRANTED** in part, and **DENIED** in part.

¹ Plaintiff Bowser’s name is improperly listed in the caption as “Suzanne Bowsver.”

I. BACKGROUND

GE manufactures, produces, distributes, and sells washing machines throughout the United States. Am. Compl. ¶ 20. Sales occur both directly to the consumer and through GE’s network of authorized dealers, which includes leading retailers and online merchants. *Id.* ¶ 21. The Amended Complaint alleges that GE’s “front-loading washer machines” have design defects that cause them to: (1) accumulate

mold and mildew, (2) produce a moldy or mildew odor that permeates the washing machines and the clothes and other items washing in the machines; and that (3) fail to remove the moisture, residue, and bacteria that lead to the formation of mold, mildew, and foul odors (collectively, the “Mold Problems”). *Id.* ¶ 2. The Amended Complaint alleges that defects in the drum, the door, and the door seal play a role in the accumulation of mold and mildew. *Id.* ¶ 39.

The Amended Complaint alleges that GE made numerous misrepresentations to conceal the design defects in its front-loading washing machines. Am. Compl. ¶ 37. Specifically, Plaintiffs allege that GE “made express representations” about the quality of its washing machines. *Id.* ¶ 24. Plaintiffs also allege that GE made “affirmations of fact and promises including those found in its advertisements, promotional and marketing materials, point-of-sale displays, product specifications, and within the washing machine manuals.” *Id.* ¶ 115. The Amended Complaint alleges that consumers received an express one-year factory warranty from GE, but does not provide any other information about this warranty. *Id.* ¶ 22. Finally, the Amended Complaint alleges that GE publicized the machines as certified ENERGY STAR products.² *Id.* ¶ 25. The Amended Complaint alleges that all of these representations were false because the washing machines were not of a merchantable quality, were not fit for their ordinary purpose, and were not energy efficient. *See id.* ¶ 37.

² Certified ENERGY STAR products are more energy efficient than regular products. *Id.* ¶ 28. In order to use the ENERGY STAR mark, manufacturers must comply with current ENERGY STAR guidelines. *Id.* ¶ 26.

The named Plaintiffs filed this action on behalf of themselves, a putative nationwide class, and a putative sub-class comprised of “[a]ll persons in Missouri, New Jersey, and Pennsylvania who own a Washing Machine for personal, family, or household purposes.” Am. Compl. ¶ 72. The Amended Complaint alleges that the putative class members were damaged because they paid far too much for defective washing machines. *Id.* ¶ 8. The Amended Complaint makes the following specific allegations with respect to the named Plaintiffs.

A. Plaintiff Fishman

*2 Fishman purchased a GE washing machine for household purposes in November 2006. Am. Compl. ¶ 53. He paid

approximately \$1,000 for the washing machine and at all times used the washing machine as instructed by GE's manual or as otherwise directed by GE. *Id.* Approximately six months after purchasing his washing machine, Fishman noticed a foul, mold, or mildew odor emanating from the machine. *Id.* Fishman contacted GE so that GE could correct the problem. *Id.* ¶ 54. GE recommended that Fishman leave his washing machine door open between washes to reduce the incidence of the Mold Problem. *Id.* ¶ 55. This recommendation did not solve the problem. *Id.* In addition, the GE owner's manual specifically warns that leaving the washer door open creates a risk of injury to children and pets who might be enticed to hang on the door or crawl inside the washer. *Id.* GE never resolved the Mold Problems in Fishman's machine, and instead provided Fishman with a check for \$75.00. *Id.* ¶ 57.

B. Plaintiff Bowser

Bowser purchased a washing machine from Builders Surplus for household purposes on or about March 3, 2007. Am. Compl. ¶ 59. She paid approximately \$579.99 for the washing machine and at all times used the washing machine as instructed by GE's manual or as otherwise directed by GE. *Id.* At some unspecified time after the purchase of her washing machine, Bowser noticed a foul, mold, or mildew odor emanating from the machine. *Id.* Bowser tried to clean her washing machine using bleach, vinegar, and Tide Washing Machine Cleaner. *Id.* ¶ 61. She also manually cleaned the visible Mold Problem from the gasket and the hose at the bottom of the machine. *Id.* She also arranged for a certified technician from Sears to attempt to remedy the Mold Problems, but these measures were unsuccessful. *Id.* Bowser contacted GE. *Id.* ¶ 62. GE recommended that Bowser keep her washing machine door open and provided her with a box of Tide Washing Machine Cleaner. *Id.* None of these measures solved the Mold Problems. *Id.* ¶ 64.

C. Plaintiff Plunkett

Plunkett purchased a washing machine from Foster's Appliance for household purposes on or about January 23, 2010. Am. Compl. ¶ 65. She paid approximately \$2023.74 for the washing machine and matching dryer, and at all times used the washing machine as instructed by GE's manual or as otherwise directed by GE. *Id.* At some unspecified time after the purchase of her washing machine, Plunkett noticed a foul, mold, or mildew odor emanating from the washing machine. *Id.* Plunkett left the door open and cleaned the unit on a regular basis, but these measures failed to correct the Mold

Problems. *Id.* Plunkett also contacted Foster's Appliance, but never received a response. *Id.* ¶ 66.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) provides for the dismissal of a complaint, in whole or in part, if the plaintiff fails to state a claim upon which relief can be granted. The moving party bears the burden of showing that no claim has been stated. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir.2005). In deciding a motion to dismiss under Rule 12(b)(6), a court must take all allegations in the complaint as true and view them in the light most favorable to the plaintiff. See *Warth v. Seldin*, 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975); *Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts Inc.*, 140 F.3d 478, 483 (3d Cir.1998).

*3 Although a complaint need not contain detailed factual allegations, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). Thus, the factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, such that it is "plausible on its face." See *id.* at 570; see also *Umland v. PLANCO Fin. Serv., Inc.*, 542 F.3d 59, 64 (3d Cir.2008). A claim has "facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. at 556). While "[t]he plausibility standard is not akin to a 'probability requirement' ... it asks for more than a sheer possibility." *Iqbal*, 129 S.Ct. at 1949 (2009).

Pursuant to Federal Rule of Civil Procedure 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the "precise misconduct with which [it is] charged." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir.2007) (quoting *Lum v. Bank of America*, 361 F.3d 217, 223–24 (3d Cir.2004)) (internal quotations omitted). To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation. *Id.*

III. DISCUSSION

2013 WL 1845615

Plaintiffs' Amended Complaint asserts six causes of action:

- (1) Count 1: Violation of the New Jersey Consumer Fraud Act ("New Jersey CFA");
- (2) Count 2: Violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("Pennsylvania UTPCPL");
- (3) Count 3: Violation of the Missouri Merchandising Practices Act ("Missouri MPA");
- (4) Count 4: Breach of Express Warranty;
- (5) Count 5: Breach of the Implied Warranty of Merchantability; and
- (6) Count 6: Unjust Enrichment.

Plaintiffs assert that New Jersey law applies to the putative nationwide class. Defendant does not dispute that New Jersey law applies for purposes of this motion.³ Defendant argues that every count of the Amended Complaint, except Count 4 (Breach of Express Warranty), is subsumed by the New Jersey Product Liability Act ("New Jersey PLA"). Defendant also argues that each of the six counts in the Amended Complaint should be dismissed. Finally, Defendant argues that the nationwide class allegations in the Amended Complaint should be "dismissed." Def.'s Br. at 13. The Court will discuss: (1) the New Jersey PLA; (2) the statutory consumer fraud claims (Counts 1–3); (3) the warranty claims (Counts 4 and 5); (4) the unjust enrichment claim (Count 6); and (5) the nationwide class allegations.

³ Defendant reserved its right to analyze each Plaintiff's claims under New Jersey's choice-of-law principles at a later stage in the litigation. *See* Def.'s Br. at 9–10 n. 4.

A. The New Jersey PLA

*⁴ Defendant argues that Plaintiffs' statutory consumer fraud, breach of implied warranty, and unjust enrichment claims are subsumed by the New Jersey PLA and should be dismissed. The Court disagrees.

The New Jersey PLA "effectively creates an exclusive statutory cause of action for claims falling within its purview." *Recola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir.1991). The statute defines a "product liability action" as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying

the claim, except actions for harm caused by breach of an express warranty." [N.J.S.A. 2A:58C-1\(b\)\(3\)](#). The statute defines "harm" caused by a product to include: "(a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; [and] (c) pain and suffering, mental anguish or emotional harm...." [N.J.S.A. 2A:58C1 \(b\)\(2\)](#).

This is not a product liability action. Defendant argues that the essence of the Amended Complaint is that mold problems in the washing machines caused damage to Plaintiffs' property (clothes and other items washed), and to Plaintiffs themselves or their children and pets. This mischaracterizes the Amended Complaint. Plaintiffs do not claim any physical injury to person (or pet) as part of their damages. Rather, the crux of Plaintiffs' allegations is that the washing machines themselves do not work as promised; *i.e.*, Plaintiffs' allege that the harm was "to the product itself." [N.J.S.A. 2A:58C-1\(b\)\(2\)](#); *see also* *Montich v. Miele USA, Inc.*, 849 F.Supp.2d 439, 457 (D.N.J.2012) (where plaintiff's claim of harm was for the "accumulation of mold inside the Miele washing machine and the resulting odor," the "damage is to the product itself and therefore falls outside the ambit of the NJPLA") (internal quotations omitted).

Accordingly, the Court finds that none of Plaintiffs' claims are subsumed by the New Jersey PLA.

B. The Statutory Consumer Fraud Claims (Counts 1–3)

In Count 1, Plaintiffs assert a claim for Violation of the New Jersey CFA, [N.J.S.A. 56:8-1, et seq.](#) In Count 2, Plaintiffs assert a claim for violation of the Pennsylvania UTPCPL, 73 P.S. § 201-1, *et seq.* In Count 3, Plaintiffs assert a claim for violation of the Missouri MPA, [Mo.Rev.Stat. § 407.010, et seq.](#) Defendant moves to dismiss all three Counts, arguing that Plaintiffs failed to plead fraud with the particularity required by [Rule 9\(b\)](#). The Court agrees.

Despite filing a 39-page, 152-paragraph Amended Complaint, Plaintiffs failed to provide basic information about key aspects of their claims. For example, Plaintiffs do not specify which washing machines they are talking about. Plaintiffs do not provide model numbers, dates of manufacture or any other information identifying precisely which products are at issue in this litigation. Further, Plaintiffs failed to provide essential dates, such as the dates on which Bowser and Plunkett discovered the alleged defect in their washing machines. Finally, Plaintiffs assert that "GE ... made

2013 WL 1845615

express representations about the quality of its washing machines" (Am.Compl.¶ 24), but do not identify what these representations were or when they were made. Without this basic information, the allegations in the Amended Complaint are not sufficient "to place the defendant [or the Court] on notice of the precise misconduct ... charged." *Frederico*, 507 F.3d at 200. And they fall woefully short of meeting Rule 9(b)'s heightened pleading standard.

*5 Accordingly, the motion to dismiss Counts 1, 2 and 3 is **GRANTED**, and Counts 1, 2 and 3 are **DISMISSED WITHOUT PREJUDICE**.

C. The Warranty Claims (Counts 4 and 5)

In Count 4, Plaintiffs assert a claim for breach of express warranty. In Count 5, Plaintiffs assert a claim for breach of the implied warranty of merchantability. Defendant moves to dismiss, arguing that Plaintiffs failed to plead plausible warranty claims. The Court agrees.

The Amended Complaint does not provide enough information to support an express warranty claim. Under New Jersey law, in order to state a claim for breach of express warranty, Plaintiffs must allege: (1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description. *N.J. Stat. Ann. § 12A:2-313*; *Arlandson v. Hartz Mountain Corp.*, 792 F.Supp.2d 691, 706 (D.N.J.2011). In this case, the Amended Complaint fails to describe the most important part of the express warranty claim: the express warranty. Plaintiffs allege that "GE has breached its written warranty" (Am.Compl.¶ 119), but Plaintiffs do not identify the actual language or source of this written warranty, or specify when the warranty was in effect. Plaintiffs also allege that Defendant made "affirmations of fact and promises including those found in its advertisements, promotional and marketing materials, point-of-sale displays, product specifications, and within the washing machine manuals." Am. Compl. ¶ 115. But Plaintiffs do not identify any specific affirmations of fact or promises, and do not provide the language of any advertisements, promotional or marketing materials, pointof-sale displays, or product specifications. Without the language of the warranty, and a start date and end date for the warranty, Plaintiffs cannot state a breach of express warranty claim. See *Arlandson*, 792 F.Supp.2d at 707 (breach of express warranty claim dismissed where plaintiffs "fail[ed] to identify the actual language or source of any

alleged warranty"); *Simmons v. Stryker Corp.*, No. 08-3451, 2008 WL 4936982, at *2 (D.N.J. Nov.17, 2008) (dismissing a claim that was "devoid of any 'factual matter' to support the existence of an express warranty").

The Amended Complaint also does not provide enough information to support an implied warranty claim. Under New Jersey law, a warranty of merchantability is implied in every contract for the sale of goods. *N.J. Stat. Ann. § 12A:2-314*. "In order for the implied warranty of merchantability to be breached, the product at issue must have been defective or not fit for the ordinary purpose for which it was intended." See *In re Toshiba Am. HD DVD Mktg. & Sales Practices Litig.*, No. 08-939, 2009 WL 2940081, at * 16 (D.N.J. Sept.11, 2009). "[A]n implied warranty cannot temporally exceed an express warranty under New Jersey law." *Weske v. Samsung Electronics Am., Inc.*, No. 10-4811, 2012 WL 833003, at *6 (D.N.J. Mar.12, 2012) (citing *N.J.S.A. 12A:2-317*). Because Plaintiffs failed to specify the start and end date of any express warranty, and failed to identify when the alleged defect arose in Bowser and Plunkett's washing machines, Plaintiffs have not established that the alleged defects arose during the implied warranty period. Thus, Plaintiffs have failed to state a claim for breach of the implied warranty of merchantability.

*6 Accordingly, the motion to dismiss Counts 4 and 5 is **GRANTED**, and Counts 4 and 5 are **DISMISSED WITHOUT PREJUDICE**.

D. The Unjust Enrichment Claim (Count 6)

In Count 6, Plaintiffs assert a claim for unjust enrichment. Defendant moves to dismiss this claim, arguing that Plaintiffs cannot recover for unjust enrichment because they did not purchase their washing machines directly from GE. The Court agrees.

Under New Jersey law, an indirect purchaser cannot succeed on a claim for unjust enrichment. "When an individual purchases a consumer product from a third-party store and not the manufacturer, the purchaser has not conferred a benefit directly to the manufacturer such that the manufacturer could be found to have been unjustly enriched." *Weske*, 2012 WL 833003, at *7; see also *Hughes v. Panasonic Consumer Electronics, Co.*, No. 10-846, 2011 WL 2976839, at *27 (D.N.J. July 11, 2011) (dismissing unjust enrichment claim on Rule 12(b)(6) motion where plaintiffs in putative class action purchased allegedly defective product from third-party sellers). Plaintiffs cite to a single case, *Stewart v. Beam Global Spirits & Wine, Inc.*, 877 F.Supp.2d 192 (D.N.J.2012)

(“*Stewart*”), holding that a plaintiff can bring an unjust enrichment claim against a manufacturer, even if the plaintiff bought the product in question from a third-party seller. *Id.* at 201. However, even the *Stewart* court acknowledged that the vast majority of courts in this District have come out the other way. *See Stewart*, 877 F.Supp.2d at 197. This Court joins the majority of courts in this District in finding that a manufacturer is not liable for unjust enrichment if plaintiffs purchased the goods in question from a third-party. It is undisputed that Plaintiffs did not purchase their washing machines directly from GE. Thus, they cannot recover from GE for unjust enrichment.

Accordingly, the motion to dismiss Count 6 is **GRANTED**, and Count 6 is **DISMISSED WITH PREJUDICE**.

E. The Nationwide Class Allegations

In a single paragraph of its motion, Defendant argues that the nationwide class allegations in the Amended Complaint should be “dismissed” “due to the differences in the consumer fraud laws of the various states across the country.” Def.’s Br. at 13. The Court disagrees. As an initial matter, the Court notes that the proper procedural mechanism for making this argument is a motion to strike under [Federal Rule of Civil Procedure 12\(f\)](#). However, even if Defendant had properly

filed a motion to strike, the Court would deny it, as any request to strike the class allegations is premature at this stage of the proceedings. *See Feldman v. Mercedes-Benz USA, LLC*, No. 11-984, 2012 WL 6596830, at * 13 (D.N.J. Dec.18, 2012) (“numerous cases in this District have emphatically denied requests to strike class allegations at the motion to dismiss stage as procedurally premature”); *Andrews v. Home Depot U.S.A., Inc.*, No. 03-5200, 2005 WL 1490474, at *3 (D.N.J. June 23, 2005) (same); *Myers v. Medquist, Inc.*, No. 05-4608, 2006 WL 3751210, at *5 (D.N.J. Dec.20, 2006) (same). Accordingly, the motion to dismiss the nationwide class allegations is **DENIED**.

IV. CONCLUSION

*7 For the reasons stated above, Defendant’s motion to dismiss is **GRANTED** in part, and **DENIED** in part. Counts 1, 2, 3, 4, and 5 are **DISMISSED WITHOUT PREJUDICE**. Count 6 is **DISMISSED WITH PREJUDICE**. The motion to dismiss the nationwide class allegations is denied. An appropriate order follows.

All Citations

Not Reported in F.Supp.2d, 2013 WL 1845615

TAB 19

 KeyCite Yellow Flag - Negative Treatment
Distinguished by [Cantonis v. Stryker Corp.](#), D.Minn., November 23, 2010

2010 WL 3905854

United States District Court, D. Minnesota.

James FORSLUND, Plaintiff,

v.

STRYKER CORPORATION, a Michigan corporation; and Stryker Sales Corporation, a Michigan corporation, Defendants.

Civil No. 09-2134 (JRT/JJK).

Sept. 30, 2010.

Attorneys and Law Firms

[Paul M. Simmons](#) and [Colin P. King](#), Dewsnap King & Olsen, Salt Lake City, UT; and [Yvonne M. Flaherty](#), Lockridge Grindal Nauen PLLP, Minneapolis, MN, for plaintiff.

[Timothy P. Griffin](#) and [Frederick W. Morris](#), Leonard Street and Deinard, P.A., Minneapolis, MN, for defendants.

MEMORANDUM OPINION AND ORDER

[JOHN R. TUNHEIM](#), District Judge.

*1 On August 13, 2009, plaintiff James Forslund filed a complaint against defendants Stryker Corporation, Stryker Sales Corporation, and Stryker Orthopaedics,¹ alleging various claims arising out of the insertion of a pain pump manufactured by Stryker into Forslund's shoulder after surgery. Forslund claims that the pain pump's continuous injection of anesthetic solutions directly into his shoulder caused permanent damage to his shoulder joint. Forslund alleges claims for strict liability, negligence, negligent misrepresentation, and breach of express and implied warranties. On September 28, 2009, Stryker filed a motion for judgment on the pleadings. Forslund opposes the motion and, in the alternative, moves for leave to amend his complaint. For the reasons set forth below, the Court grants Stryker's motion, dismissing Forslund's complaint without prejudice in part and with prejudice in part; and grants Forslund's motion for leave to amend.

1 On October 16, 2009, the parties stipulated to the dismissal of Stryker Orthopaedics from the case. (Docket No. 25.)

BACKGROUND²

2 For the purposes of the motion to dismiss, the Court accepts the factual allegations contained in the complaint as true. *Bhd. of Maint. of Way Employees v. Burlington N. Santa Fe R.R.*, 270 F.3d 637, 638 (8th Cir.2001) (per curiam); *see also Ashcroft v. Iqbal*, — U.S. —, 129 S.Ct. 1937, 1949 (2009).

On or about December 29, 2005, Forslund underwent shoulder surgery. (Compl. ¶ 5, Docket No. 1.) After the operation, a pain pump designed and manufactured by Stryker was implanted in Forslund's shoulder. (*Id.* ¶¶ 5, 12.) The pain pump is a medical device that "deliver[s] a continuous and rate-controlled amount of pain medication, via catheter, directly to a surgical site, including the joint space, for post-surgical pain management." (*Id.* ¶ 7.) Stryker "designed, manufactured, sold, and/or distributed [the pain pumps] with the intent ... that they be used with a reservoir of anesthetic solution for 48 hours or more." (*Id.* ¶ 9.) According to the complaint, "the continuous injections of anesthetic solutions ... directly into or in the vicinity of the shoulder joint, can cause and has caused catastrophic and permanent damage to ... [Forslund's] shoulder joint, resulting in severe and unremitting pain, weakness, loss of strength, decreased range of motion, and other profound injuries." (*Id.*) As a result, Forslund "has been left severely and permanently disabled." (*Id.* ¶ 10.)

Forslund alleges six claims against Stryker for (1) strict liability (design defect and failure to warn), (2) negligence (design defect and failure to warn), (3) negligent misrepresentation, (4) breach of express warranty, (5) breach of implied warranty of merchantability, and (6) breach of implied warranty of fitness for a particular purpose. On September 28, 2009, Stryker filed a motion for judgment on the pleadings. Forslund opposes the motion and alternatively requests leave to file an amended complaint pursuant to [Federal Rule of Civil Procedure 15\(a\)\(2\)](#).

DISCUSSION

I. STANDARD OF REVIEW

Rule 12(c) of the Federal Rules of Civil Procedure provides that “[a]fter the pleadings are closed ... a party may move for judgment on the pleadings.” A motion for judgment on the pleadings is analyzed under the same standard as a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). See *Westcott v. Omaha*, 901 F.2d 1486, 1488 (8th Cir.1990). The Court considers all facts alleged in the complaint as true, and construes the pleadings in a light most favorable to the non-moving party. See, e.g., *Bhd. of Maint. of Way*, 270 F.3d at 638. To survive a motion for judgment on the pleadings, however, a complaint must provide more than “‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action.’” See *Ashcroft v. Iqbal*, — U.S. —, 129 S.Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). That is, to avoid dismissal, a complaint must include “sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Id.* (internal quotation marks omitted). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* “Where a complaint pleads facts that are merely consistent with a defendant’s liability, it stops short of the line between possibility and plausibility,” and therefore must be dismissed. *Id.* (quoting *Twombly*, 550 U.S. at 557) (internal quotation marks omitted).

II. FORSLUND’S ORIGINAL COMPLAINT

A. Strict Liability (Count 1)

*2 Forslund raises two strict liability claims in his complaint, alleging that the pain pump was defectively designed and that the pain pump was defective because Stryker failed to provide adequate warnings and instructions. Stryker argues that Forslund has not pleaded facts sufficient to establish either strict liability claim.

1. Design Defect

To recover for strict liability under Minnesota products liability law, “the plaintiff must establish (1) that the defendant’s product was in a defective condition unreasonably dangerous for its intended use, (2) that the defect existed when the product left the defendant’s control, and (3) that the defect was the proximate cause of the injury sustained.” *Bilotta v. Kelly Co., Inc.*, 346 N.W.2d 616, 623 n. 3 (Minn.1984); *Drager v. Aluminum Indus. Corp.*, 495 N.W.2d 879, 882 (Minn.Ct.App.1993). “Minnesota merges negligence and strict liability claims into a single products liability theory, which employs a reasonable-care balancing test to determine

whether a product is defective.” *Thompson v. Hirano Tecseed Co., Ltd.*, 456 F.3d 805, 809 (8th Cir.2006); *Trost v. Trek Bicycle Corp.*, 162 F.3d 1004, 1009 (8th Cir.1998) (“The reasonable care balancing test is used in Minnesota to determine if a product was designed in a defective condition unreasonably dangerous for its intended use.” (internal quotation marks omitted)). To determine whether a product is unreasonably dangerous in its design, the Court balances “the likelihood of harm, and the gravity of harm if it happens, against the burden of the precaution which would be effective to avoid the harm.” *Bilotta*, 346 N.W.2d at 621; accord *Trost*, 162 F.3d at 1009. “The test is an objective standard ‘which focuses on the conduct of the manufacturer in evaluating whether its choice of design struck an acceptable balance among several competing factors.’” *Trost*, 162 F.3d at 1009 (quoting *Bilotta*, 346 N.W.2d at 622); see also *Young v. Pollock Eng’g Group, Inc.*, 428 F.3d 786, 789 (8th Cir.2005).

Forslund alleges that “the pain pump was defectively designed and manufactured by the Defendants in that the continuous feed of post-surgical anesthetic solution at the delivery rate used by the pain pump caused permanent injury.” (Compl.¶ 13(a), Docket No. 1.) Forslund also alleges that the pain pump’s delivery of anesthetic solutions directly to the shoulder joint caused “catastrophic and permanent damage” to Forslund’s shoulder joint, (*id.* ¶ 9); that the Food and Drug Administration (“FDA”) denied Stryker’s application to permit the use of pain pumps in the shoulder joint space, (*id.* ¶ 13(g)); and that continuous injection of anesthetics into the shoulder joint by the pain pump “is very likely to cause serious and permanent injury to the joint,” (*id.* ¶ 13(d)).

Forslund alleges only conclusory statements that the pain pump is unreasonably dangerous in its design. Reciting the elements of the reasonable-care balancing test, Forslund alleges that the pain pump’s continuous injection of anesthetic solutions directly into the shoulder joint “is very likely to cause permanent injury,” but Forslund does not allege facts supporting that conclusion. Although Forslund characterizes the potential harm caused by that defect as “catastrophic and permanent,” Forslund does not allege facts identifying the burden on Stryker to adopt a precaution that would avoid such harm. Forslund’s claim boils down to an allegation that the pain pump is defective and unreasonably dangerous in its design because it is “very likely” to cause serious harm. Consequently, Forslund’s complaint does not allege sufficient facts to plead a plausible design defect claim under Minnesota law. See *Iqbal*, 129 S.Ct. at 1949 (“Nor does a

complaint suffice if it tenders naked assertions devoid of further factual enhancement.” (internal quotation marks and alteration omitted).³

³ Forslund has clarified that he did not intend to and does not now assert a claim for defective manufacturing. (PL's Mem. in Opp'n to Defs.' Mot. for J. on Pleadings at 6 n. 30, Docket No. 29.)

2. Failure to Warn

*³ Forslund alleges that Stryker “marketed, sold, and/or distributed the [] pain pumps specifically to be used directly in the shoulder joint space.” (Compl. ¶ 13(g), Docket No. 1.) Forslund alleges that Stryker “failed to provide adequate warnings and instructions concerning the risks presented by (i) using a higher dosage of pain medication, (ii) inserted into the surgical site, and (iii) for an extended period of time.” (*Id.* ¶ 13(b).) Forslund also claims that the pain pump's “instructions and labeling failed to include a precaution against placing the catheter of the [] pain pumps in or near the joint space,” and that the pain pump's “instructions and labeling failed to provide [Forslund], his surgeon, or the United States medical community at large adequate instructions and warnings for safe use of the [] pain pumps in or near the joint shoulder space.” (*Id.* ¶ 13(e)-(f), Docket No. 1.) Forslund alleges that the defective warnings rendered the pain pumps unreasonably dangerous. (*Id.* ¶ 13(h).)

Stryker argues that Forslund's complaint does not establish a failure-to-warn claim because it does not plead facts (1) identifying the use for which the Stryker pain pump was designed and marketed; (2) showing that Forslund's surgeon used the pain pump in the manner for which it was designed and marketed; (3) demonstrating that Stryker knew or should have known that the pain pump was likely to be dangerous for its intended use; or (4) indicating that Stryker failed to use reasonable care in informing Forslund's surgeon that certain uses of the pain pump could be unreasonably dangerous. (Defs.' Mem. in Supp. of Mot. for J. on the Pleadings at 9, Docket No. 18.)

“[A] supplier has a duty to warn end users of a dangerous product if it is reasonably foreseeable that an injury could occur in [the] use [for which it is supplied].”⁴ *Gray v. Badger Min'g Corp.*, 676 N.W.2d 268, 274 (Minn.2004); see also *Gamradt v. Federal Lab., Inc.*, 380 F.3d 416, 419 (8th Cir.2004) (applying Minnesota law). “The duty to warn has been described as two duties: (1) The duty to give

adequate instructions for safe use; and (2) the duty to warn of dangers inherent in improper usage.” *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 787 (Minn.1977). “[W]here the manufacturer ... of a product has actual or constructive knowledge of danger to users, the ... manufacturer has a duty to give warning of such dangers.” *Id.* at 788. “To be legally adequate, the warning should (1) attract the attention of those that the product could harm; (2) explain the mechanism and mode of injury; and (3) provide instructions on ways to safely use the product to avoid injury.” *Gray*, 676 N.W.2d at 274.

⁴ The Minnesota Supreme Court “has adopted the position that strict liability for failure to warn is based upon principles of negligence.” *Germann v. F.L. Smithe Mach. Co.*, 395 N.W.2d 922, 926 n. 4 (Minn.1986).

With respect to the use or purpose for which the pain pump was designed, Forslund contends that Stryker “designed and marketed pain pumps for use directly in the shoulder joint space.” (Pl.'s Mem. in Opp'n to Mot. for J. on the Pleadings at 9, Docket No. 29.) Forslund's complaint, however, alleges only that Stryker designed and manufactured the pain pumps for use in “the joint space.” (Compl. ¶ 7, Docket No. 1.) From that language, the Court is required to make a significant assumption that Stryker intended the pain pumps be used in shoulder joint spaces. Given the disjointed, vague allegations in the complaint, the Court declines to draw such an inference.

*⁴ Forslund also alleges that Stryker failed to take reasonable care to inform Forslund's surgeon of the dangers inherent in the intended use of or misuse of the pain pump, (*see id.* ¶ 20(d)), but Forslund does not allege facts supporting that conclusion. Indeed, Forslund does not allege facts showing that Stryker knew or should have known that the pain pump would be dangerous for the use for which it was supplied.⁵ Accordingly, Forslund's complaint does not allege sufficient facts to support a plausible claim for relief for failure to warn.

⁵ Forslund alleges that the FDA did not approve the pain pump for use in the shoulder joint space. (*Id.* ¶ 13(g).) That allegation, however, is not probative of whether Stryker knew or should have known of the risks relating to the use of the pain pump in the shoulder joint space and therefore that Stryker had a duty to warn about that potential use. Forslund also filed a supplemental declaration with his opposition to Stryker's motion, which includes

an FDA advisory relating to the use of pain pumps in joint spaces. Because that declaration is not necessarily embraced by the pleadings, the Court declines to consider that exhibit in this motion. *See Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir.1999).

3. Redundant Claims

Stryker also contends that the Court should dismiss Forslund's strict liability claims for design defect and failure to warn for the additional reason that they would be redundant with Forslund's negligence claims. (Defs.' Mem. in Supp of Mot. for J. on the Pleadings at 7, 10, Docket No. 18.) Minnesota law merges strict liability and negligence theories under a single products liability theory and analyzes design defect claims under the reasonable-care balancing test. *See Thompson*, 456 F.3d at 809. Forslund, however, does not need to decide at this stage of the litigation whether he will pursue his strict liability claims or negligence claims. Although Forslund will eventually have to choose only one of those claims to submit to the jury, Forslund "can plead and prove at trial either or both theories," and then determine which theory to submit to the jury. *Hauenstein v. Loctite Corp.*, 347 N.W.2d 272, 275 (Minn.1984); *cf. Bilotta*, 346 N.W.2d at 622 ("Whether strict liability or negligence affords a plaintiff the broader theory of recovery will depend largely on the scope of evidence admitted by the trial court and on the jury instructions given under each theory.").

For the reasons stated above, the Court dismisses without prejudice Forslund's strict liability design defect and failure to warn claims.

B. Negligence (Count 2)

In addition to his strict liability claims, Forslund brings claims for negligent design and negligent failure to warn. Stryker argues that the Court should dismiss the negligence claims because they are redundant with his strict liability claims. Forslund responds that because his negligence cause of action incorporates the prior allegations—including his strict liability allegations—in the complaint, he has stated a claim for negligence:

The same facts from which a jury could conclude that [Stryker's] pain pump was defectively designed also support a claim that [Stryker] failed to

exercise reasonable care in designing the pain pump, and the same facts from which a jury could conclude that the pain pump was defective because it was not accompanied by adequate warnings and instructions regarding its use also support a claim that [Stryker was] negligent in not providing proper warnings.

(Pl.'s Mem. in Opp'n to Defs.' Mot. for J. on the Pleadings at 12, Docket No. 29.)

To the extent that Forslund's negligence allegations rely on the preceding allegations of fact and allegations relating to his strict liability claims, the Court similarly concludes that Forslund has not adequately pleaded his negligence claims under the reasonable-care balancing test.⁶ *See, e.g., Westbrock v. Marshalltown Mfg. Co.*, 473 N.W.2d 352, 356 (Minn.Ct.App.1991) ("Bilotta merged strict liability [and] negligence ... remedies into a single products liability theory. To recover, an injured party must show (1) the product was in a defective condition, unreasonably dangerous to the user, (2) the defect existed when the product left the manufacturer's control, and (3) causation. The [Minnesota] supreme court fused a negligence standard into a traditional strict liability theory by employing a reasonable care balancing test to determine whether the product was defective." (citations omitted)); *see also Germann v. F.L. Smithe Mach. Co.*, 395 N.W.2d 922, 926 n. 4 (Minn.1986). Accordingly, the Court dismisses without prejudice Forslund's negligence claims.

⁶

"The distinction between strict liability and negligence in design-defect and failure-to-warn cases is that in strict liability, knowledge of the condition of the product and the risks involved in that condition will be imputed to the manufacturer, whereas in negligence these elements must be proven." *Bilotta*, 346 N.W.2d at 622.

*⁵ As noted above, however, the negligence claims are not redundant with the strict liability claims at this stage of the litigation, and Forslund may plead both theories in his complaint. *See Hauenstein*, 347 N.W.2d at 275.

C. Negligent Misrepresentation (Count 3)

Forslund alleges that Stryker negligently misrepresented and communicated false information to Forslund and his surgeon that the “pain pumps were safe, effective, and would not harm or adversely affect ... Forslund’s health.” (Compl. ¶ 26, Docket No. 1.) Forslund further alleges that Stryker knew those representations to be false, that he and his surgeon reasonably relied on those representations, and that the misrepresentations proximately caused him damages. (*Id.* ¶¶ 26–29.)

Stryker asks the Court to dismiss Forslund’s negligent misrepresentation claim for two reasons: First, Stryker contends that Forslund has not pled his negligent misrepresentation claim with particularity as required under **Federal Rule of Civil Procedure 9(b)**. Second, Stryker argues Forslund may not recover under a negligent misrepresentation theory because Minnesota law only permits a party to recover pecuniary damages for negligent misrepresentation and, here, Forslund alleges personal injury.

1. Federal Rule of Civil Procedure 9(b)

To establish a claim for negligent misrepresentation, Forslund must demonstrate that “(1) [Stryker] owe [d] him a duty of care in obtaining or communicating information; (2) [Stryker] supplied false information in breach of that duty of care; (3) [Forslund] justifiably relied on the false information; and (4) [Forslund] was damaged as a result.” *See Masepohl v. Am. Tobacco Co., Inc.*, 974 F.Supp. 1245, 1251 (D.Minn.1997).

Forslund must plead his claim for negligent misrepresentation with particularity as required under **Federal Rule of Civil Procedure 9(b)**. *McGregor v. Uponor, Inc.*, Civ. No. 09–1136, 2010 WL 55985, at *3 (D.Minn. Jan. 4, 2010) (“Minnesota law holds that allegations of ... negligent misrepresentation [] sound in fraud and therefore must satisfy the pleading requirements of Rule 9(b).”); *ADT Sec. Servs., Inc. v. Swenson*, No. Civ. 07–2983, 2008 WL 2828867, at *4 (D.Minn. July 21, 2008); *see also McLain v. Andersen Corp.*, 567 F.3d 956, 970 (8th Cir.2009). A claim for negligent misrepresentation must generally plead circumstances “includ [ing] such matters as the time, place and contents of false representations, as well as the identity of the person making the misrepresentation and what was obtained or given up thereby.” *Murr Plumbing, Inc. v. Scherer Bros. Fin. Servs. Co.*, 48 F.3d 1066, 1069 (8th Cir.1995).

Forslund’s allegations do not identify who made the representations to Forslund or his surgeon, the content of those representations, or when the representations were

made. As a consequence, the complaint does not allege facts by which to determine that the representations were false at the time they were made. Accordingly, Stryker is entitled to judgment on the pleadings on Forslund’s negligent misrepresentation claim because Forslund has not pleaded that claim with particularity.

2. Pecuniary Damages

*6 Stryker also argues that Forslund’s negligent misrepresentation claim should be dismissed because it does not arise out of a business or commercial setting and seek damages for pecuniary loss. The Minnesota Supreme Court has held:

One who, in the course of his business, profession or employment, or in a transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

Bonhiver v. Graff, 248 N.W.2d 291, 298 (Minn.1976).

Forslund contends that although the Minnesota Supreme Court has not permitted claims for negligent misrepresentation involving the risk of physical harm, the Supreme Court has also not “foreclose [d] the possibility of recognizing in Minnesota the tort of negligent misrepresentation involving the risk of physical harm.” *Smith v. Bruger Cos.*, 569 N.W.2d 408, 411 (Minn.1997). Alternatively, Forslund argues that he has pleaded that Stryker’s alleged statements were made in a business or commercial setting or in a setting in which Stryker had a pecuniary interest, and that Forslund suffered pecuniary loss in the form of extensive medical bills and follow-up care by relying on those representations. (Pl.’s Mem. in Opp’n to Mot. for J. on Pleadings at 15, Docket No. 29.)

Putting aside Forslund’s inability to plead the negligent misrepresentation claim with particularity, Forslund has not

stated a claim for negligent misrepresentation as a matter of law. Forslund offers no support for the argument that while the Minnesota Supreme Court has not foreclosed the possibility of recognizing a negligent misrepresentation claim for physical harm, Minnesota law would permit such a claim here. Moreover, in the Court's view, if medical bills constituted pecuniary loss in these circumstances, the Minnesota Supreme Court would have recognized negligent-misrepresentation claims involving allegations of physical harm. The court has not done so, however, and has instead limited the scope of a negligent misrepresentation claim to a commercial or business setting with consequent pecuniary loss. *See Bonhiver*, 248 N.W.2d at 298. Because Forslund's injuries do not arise out of a business or commercial setting in which he had suffered pecuniary harm, the Court dismisses with prejudice Forslund's negligent misrepresentation claim.

D. Breach of Express Warranty (Count 4)

In his fourth cause of action for breach of express warranty, Forslund alleges “[o]n information and belief, [Stryker] ... expressly communicated to ... Forslund's surgeon that the pain pump was appropriate for use in or near the shoulder joint, and ... Forslund's surgeon reasonably relied on that statement in choosing to use [Stryker's] pain pump in or near ... Forslund's shoulder joint.” (Compl. ¶ 31, Docket No. 1.) Stryker argues that the Court should dismiss Forslund's breach of express warranty claim because the complaint does not allege a plausible claim for relief under that theory.

*7 Under Minnesota law, an express warranty is “[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.” *Minn.Stat. § 336.2–313(1)(a)*. “It is not necessary to the creation of an express warranty that the seller use formal words such as ‘warrant’ or ‘guarantee’ or that the seller have a specific intention to make a warranty[.]” *Id. § 336.2–313(2)*.

Although Forslund may plead his claims on information and belief, Forslund's allegations lack any factual support. The complaint does not identify who made affirmations or promises about the pain pump, to whom those statements were made, or the general terms of those statements. Although standard notice pleading practice may not require Forslund to plead all such facts, *see Fed.R.Civ.P. 8*, Forslund's allegations are so deficient as to render the breach of express warranty claim implausible on its face. Accordingly, the Court dismisses that claim without prejudice.

E. Breach of Implied Warranty of Merchantability

(Count 5)

Forslund alleges that Stryker's pain pumps, at the time they were placed in the stream of commerce “were not fit for the ordinary purposes for which such products are intended and were unmerchantable to users and consumers, including Plaintiff James Forslund.” (Compl. ¶ 36, Docket No. 1.)

Stryker contends that in a personal injury case, where a defect is alleged to render a product unfit for its ordinary purpose under implied warranty, the claim sounds in tort and is merged under the strict liability doctrine. *See Masepohl*, 974 F.Supp. at 1253. As a result, Stryker argues that Forslund's claim for breach of implied warranty of merchantability is redundant. (Defs.' Mem. in Supp. of Mot. for J. on Pleadings at 15, Docket No. 18.)

Under *Minnesota Statute § 336.2–314*, “a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind.” *Minn.Stat. § 336.2–314*. The implied warranty of merchantability assures that a product is “fit for the ordinary purposes for which such goods are used.” *Id. § 336.2.314(2)* (c); *Peterson v. Bendix Home Sys., Inc.*, 318 N.W.2d 50, 53 (Minn.1982). “To prevail on an implied warranty claim, a plaintiff must prove (1) the existence of a warranty; (2) a breach; and (3) a causal link between the breach and the alleged harm.” *Masepohl*, 974 F.Supp. at 1253.

Forslund's claim for breach of implied warranty of merchantability fails as a matter of law. “Strict products liability has effectively preempted implied warranty claims where personal injury is involved.” *Id.* (internal quotation marks and alteration omitted); *see also Nimeth v. Prest Equip. Co.*, No. C1–93–685, 1993 WL 328767, at *1 (Minn.Ct.App. Aug. 31, 1993) (citing *Continental Ins. Co. v. Loctite Corp.*, 352 N.W.2d 460, 462 (Minn.Ct.App.1984)); *Goblirsch v. Western Land Roller Co.*, 246 N.W.2d 687, 690 (Minn.1976)). Because Forslund's complaint alleges strict products liability claims and personal injury, Forslund's claim for breach of implied warranty of merchantability is preempted. Accordingly, the Court dismisses with prejudice Forslund's breach of implied warranty of merchantability claim.

F. Breach of Implied Warranty of Fitness for a Particular Purpose (Count 6)

*8 Forslund alleges that the Stryker pain pump, at the time it was placed in the stream of commerce, “was not fit for the particular purpose for which it was used by ... Forslund and his surgeon.” (Compl. ¶ 39, Docket No. 1.)

Stryker argues the Court should dismiss the claim for breach of implied warranty of fitness for a particular purpose because Stryker did not deal directly with Forslund, Stryker had no knowledge of Forslund's particular needs, and the complaint does not allege facts that Forslund relied on Stryker's expertise in electing to have the pain pump implanted in his shoulder. (Defs.' Mem. in Supp. of Mot. for J. on Pleadings at 17, Docket No. 18.) Stryker refers to this failure as a lack of “vertical privity.” Stryker also contends that the complaint does not identify Forslund's “particular purpose.”

Under [Minnesota Statute § 336.2–315](#), “[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified ... an implied warranty that the goods shall be fit for such purpose.” [Minn.Stat. § 336.2–315](#). To establish a claim for breach of an implied warranty of fitness for a particular use, Forslund must establish that: “(1) the seller had reason to know of the buyer's particular purpose; (2) the seller had reason to know that the buyer was relying on the seller's skill or judgment to furnish appropriate goods; and (3) the buyer's actual reliance.” [Driscoll v. Standard Hardware, Inc.](#), 785 N.W.2d 805, 2010 WL 2813532, at *10 (Minn.Ct.App. July 20, 2010).

As an initial matter, Forslund's failure to plead vertical privity is not dispositive, because as a surgical patient, it is reasonable to expect that Forslund would use or be affected by the Stryker pain pump. See [Minn.Stat. § 336.2–318](#) (“A seller's warranty whether express or implied extends to any person who may reasonably be expected to use, consume or be affected by the goods and who is injured by breach of the warranty.”).

Forslund's allegations, however, merely recite the elements of the claim. Forslund does not allege any facts identifying the “particular purpose” for which the pain pump was supplied or indicating that Forslund or his surgeon relied on Stryker's skill or judgments in electing to use the pain pump. Thus, the claim is not plausible on its face. See [Iqbal](#), 129 S.Ct. at 1949–50 (internal quotation marks omitted). Accordingly, the Court dismisses without prejudice Forslund's claim for breach of implied warranty of fitness for particular purpose.

III. FORSLUND'S REQUEST FOR LEAVE TO AMEND UNDER RULE 15(a)(2)

Forslund filed a conditional motion for leave to amend the complaint. (See Docket No. 30.) Under [Federal Rule of Civil Procedure 15\(a\)\(2\)](#), leave to amend “shall be freely given where justice so requires.” “A district court may appropriately deny leave to amend where there are compelling reasons such as undue delay, bad faith, or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the non-moving party, or futility of the amendment.” [Moses.com Secs., Inc. v. Comprehensive Software Sys., Inc.](#), 406 F.3d 1052, 1065 (8th Cir.2005) (internal quotation marks omitted).

*9 Stryker argues that the Court should deny Forslund's request for leave to amend, asserting that the proposed First Amended Complaint, (see Ex. 1, Docket No. 30), does not address the shortcomings of the original complaint. Stryker, however, does not argue that Forslund has unduly delayed these proceedings, acted in bad faith, or repeatedly failed to cure deficiencies in his complaint. Further, the Court's guidance in this Order provides Forslund with a better understanding of deficiencies in the original complaint, and Forslund may file an amended complaint addressing those deficiencies within thirty days of this Order.

To summarize: the Court dismisses with prejudice Forslund's third and fifth causes of action for negligent misrepresentation and breach of implied warranty of merchantability as not supported by the facts pleaded or the applicable law. The Court dismisses without prejudice the remaining claims, and grants Forslund leave to amend the complaint consistent with the Court's reasoning in this Order.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Stryker's Motion for Judgment on the Pleadings [Docket No. 16] is **GRANTED** as follows:

- a. Count 3 for negligent misrepresentation and Count 5 for breach of implied warranty of merchantability are **DISMISSED with prejudice**.
- b. Count 1 for strict liability, Count 2 for negligence, Count 4 for breach of express warranty, and Count 6 for breach

of implied warranty of fitness for a particular purpose are
DISMISSED without prejudice.

2. Forslund's Conditional Motion for Leave to Amend the Pleadings [Docket No. 30] is **GRANTED**. Forslund may file an amended complaint within thirty (30) days of the filing of this Order.

All Citations

Not Reported in F.Supp.2d, 2010 WL 3905854, 72 UCC Rep.Serv.2d 1088

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TAB 20

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United States District Court,
S.D. Iowa, Central Division.

Austin GLICK, Plaintiff,

v.

LEATT CORPORATION, and Western Power
Sports, Inc. d/b/a Fly Racing, Defendants.

Case No. 4:17-CV-00291-SMR-RW

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Signed 05/03/2018

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ORDER ON MOTION TO DISMISS

[STEPHANIE M. ROSE](#), JUDGE

*1 Plaintiff Austin Glick alleges he was injured on August 20, 2015, in Madison County, Iowa when a neck brace caused and/or failed to protect him from serious bodily injury. Plaintiff filed this lawsuit against the makers and sellers of the brace, Defendants Leatt Corporation (“Leatt”) and Western Power Sports, Inc. d/b/a Fly Racing (“Western Power Sports”), on August 7, 2017. [ECF No. 1]. Glick is suing Defendants for strict products liability, breach of warranty, negligence, gross negligence, and consumer fraud. [ECF No. 10]. On October 12, 2017, Leatt filed a Motion to Dismiss for Failure to State a Claim. [ECF No. 13]. Glick responded on October 26, 2017. [ECF No. 15]. The parties did not request oral argument, and the Court finds this matter can be resolved without it. *See* LR 7(c). For the reasons set forth below, Leatt's Motion to Dismiss, [ECF No. 13], is GRANTED.

I. BACKGROUND¹

¹ The facts come from the Amended Complaint, [ECF No. 10], and are assumed true for the purposes of the Motion to Dismiss. *See Brown v. Medtronic, Inc.*, 628 F.3d 451, 459 (8th Cir. 2010) (indicating courts must accept as true the plaintiff's factual allegations, but they need not accept as true the plaintiff's legal conclusions).

Glick is twenty-nine years old and a resident of Des Moines, Iowa. [ECF No. 10 ¶ 1]. Leatt is a Nevada corporation. *Id.* ¶ 2. Western Power Sports is an Idaho corporation. *Id.* ¶ 3. Glick alleges Defendants designed, assembled, and manufactured a product called the “Fly Racing Leatt Pro Lite Carbon Brace” (the “brace”) prior to August 20, 2015. *Id.* ¶¶ 2, 3, 5, 7. Glick also alleges Defendants advertised, distributed, and otherwise sold the brace in Southern Iowa. *Id.* ¶¶ 2, 3.

On August 20, 2015, Glick was injured in Madison County, Iowa. *Id.* ¶ 8. At the time of the injury, Glick alleges he was using the neck brace in a reasonably foreseeable manner, but he does not describe how he was using the brace. *Id.* ¶¶ 8, 14. In fact, Glick does not allege whether he purchased the brace, only that he obtained the brace and chose to wear it. *Id.* ¶ 54. Glick also alleges the brace caused and/or failed to protect him from serious bodily injury. *Id.* ¶ 8. Glick alleges his injury is permanent and disabling in nature. *Id.* ¶ 15. According to Glick, Defendants “represented that the brace would protect a rider from [spinal cord injury](#) ... that the brace was safe for use with standard motocross gear, that the brace was safe for motocross riding ... and that the brace would not cause or exacerbate injury to the rider in the event of an accident.” *Id.* ¶¶ 52, 53. However, Glick does not describe in any detail the nature of his injuries, how the brace caused his injuries, nor how it failed to protect him.

Rather, these facts are the only facts contained in the Amended Complaint. *See* [ECF No. 10]. The remaining allegations in the Amended Complaint are legal conclusions and statements reciting the elements of the causes of action, and Glick fails to provide facts supporting these assertions. Accordingly, Leatt argues Glick has failed to state a claim upon which relief can be granted pursuant to [Federal Rule of Civil Procedure 12\(b\)\(6\)](#). [ECF No. 13]. Glick attempts to supplement the facts contained in his Amended Complaint by providing additional facts in his response to Leatt's Motion to Dismiss. [ECF No. 15 at 3]. However, in analyzing a motion to dismiss the Court is limited to reviewing the facts contained in the Amended Complaint. *See Riley v. St. Louis Cty. of Mo.*, 153 F.3d 627, 629 (8th Cir. 1998) (“When reviewing a [Rule 12\(b\)\(6\)](#) dismissal for failure to state a claim, we look only to

the facts alleged in the complaint and construe those facts in the light most favorable to the plaintiff.”).

II. STANDARD OF REVIEW

*2 Rule 12(b)(6) permits a motion to dismiss for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). A complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). To meet this standard, and thus survive a motion to dismiss under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 594 (8th Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). A claim is plausible on its face “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. Although the plausibility standard “is not akin to a ‘probability requirement,’” it demands “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). “The facts alleged in the complaint ‘must be enough to raise a right to relief above the speculative level.’” *Clemons v. Crawford*, 585 F.3d 1119, 1124 (8th Cir. 2009) (quoting *Drobnak v. Andersen Corp.*, 561 F.3d 778, 783 (8th Cir. 2009)). All reasonable inferences must be drawn in the plaintiff’s favor. *Crooks v. Lynch*, 557 F.3d 846, 848 (8th Cir. 2009).

III. ANALYSIS

As an initial matter, the Court notes that Glick fails to resist Leatt’s motion to dismiss as to Counts Three and Four. Accordingly, the Court grants Leatt’s motion to dismiss on these Counts. See *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1073 (8th Cir. 2016) (noting that an issue not argued or briefed on a motion to dismiss is considered waived). However, as indicated below the Court determines that Counts Three and Four also fail to adequately state a claim for which relief may be granted, and are subject to dismissal on this ground as well.

Ordinarily, on a motion to dismiss, this Court would analyze the complaint count by count, stating the elements of the causes of action, and then determining whether the plaintiff had alleged “sufficient factual matter, accepted as true, to state

a claim to relief that is plausible on its face.” *Braden*, 588 F.3d at 594 (quoting *Iqbal*, 556 U.S. at 678). However, in the present case, Glick’s Amended Complaint alleges so few facts that the Court declines to address each count separately. Based on the facts alleged in the Amended Complaint, the Court lacks such elementary facts such as how Glick became injured, how Glick obtained the Defendant’s brace, or how Glick was using the brace when it allegedly caused or failed to protect him from injury.

The Amended Complaint does allege “the brace was being used in a reasonably foreseeable manner by Plaintiff.” [ECF No. 10 ¶ 8]. But this statement is a legal conclusion. It tells the Court nothing about how Glick was actually using the brace. Although a complaint does not need to provide “detailed factual allegations” ... ‘naked assertion[s]’ devoid of ‘further factual enhancement,’” are insufficient. *Iqbal*, 556 U.S. at 678 (alteration in original) (citations omitted) (quoting *Twombly*, 550 U.S. at 555, 557). Further, “[a] pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action will not do.’” *Id.* at 678 (quoting *Twombly*, 550 U.S. at 555). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.*

Moreover, the remaining allegations in Glick’s Amended Complaint are also nothing more than legal conclusions and statements reciting the elements of the causes of actions. See *id.* (“[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.”). For instance, Glick argues that his strict products liability claim should proceed as a design defect claim. [ECF No. 15 at 6]. Under Iowa law this requires that the plaintiff prove “the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design” *Wright v. Brooke Grp. Ltd.*, 652 N.W.2d 159, 168 (Iowa 2002). However, Glick’s Amended Complaint merely states that “[a] reasonable alternative safe design could have been practically adopted at the time of sale and/or distribution of the brace.” [ECF No. 10. ¶ 13]. This is a legal conclusion, unsupported by any other facts. Here, the Amended Complaint fails to “contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face,’” and the “facts do not permit the [C]ourt to infer more than the mere possibility of misconduct,” which means Glick has not shown he is entitled to relief. See *Iqbal*, 556 U.S. at 678–79 (quoting *Twombly*, 550 U.S. at 570).

IV. CONCLUSION

*3 For the foregoing reasons and others stated in Leatt's brief, Leatt's Motion to Dismiss, [ECF No. 13], is GRANTED. Consequently, Glick's claims against Leatt are dismissed in their entirety.

IT IS SO ORDERED.

All Citations

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TAB 21

 KeyCite Yellow Flag - Negative Treatment
Called into Doubt by *Fidelity and Guar. Ins. Underwriters, Inc. v. Omega Flex, Inc.*, D.N.J., March 26, 2013

2012 WL 1018842

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Charles HAMMER, on behalf of herself
and all others similarly situated, Plaintiffs

v.

VITAL PHARMACEUTICALS, INC. d/b/a VPX;
ABC Cos. nos. 1–100; John Does Nos. 1–100;
XYZ Cos Nos. 1–100; Robert Roes Nos. 1–
100, DEF Cos. Nos. 1–100 and John Smiths
Nos 1–100 and (fictitious names), Defendants.

Civil Action No. 11–4124.

March 26, 2012.

Attorneys and Law Firms

Frank V. Floriani, Sullivan, Papain, Block, McGrath & Cannavo, PC, Hackensack, NJ, for Plaintiffs.

George H. Parsells, McElroy, Deutsch, Mulvaney & Carpenter, LLP, Morristown, NJ, for Defendants.

OPINION

WOLFSON, District Judge.

***1** This putative class action brought by Plaintiff Charles Hammer (“Hammer” or “Plaintiff”) challenges the marketing and sales practices of Liquid Clenbutrx Hardcore (“Clenbutrx”), a “dietary supplement” manufactured by Defendant Vital Pharmaceuticals, Inc. d/b/a VPX/REDLINE (improperly pled as Vital Pharmaceuticals, Inc. d/b/a VPX) (“VPX” or “Defendant”). In the Complaint, Plaintiff alleges that Defendant’s advertisements and packaging of Clenbutrx contained various affirmative misrepresentations concerning the supplement that were deceptive and misleading, that Plaintiff purchased the products pursuant to these misrepresentations, and he suffered damages as a result thereof. Based on these averments, Plaintiff asserts violations of the New Jersey Consumer Fraud Act, *N.J.S.A. § 56:8–1 et seq.* (“NJCFA”) (Count I), as well as claims for common law fraud (Count II), unjust enrichment (Count

III), breaches of express (Count IV) and implied warranties (Count V) and injunctive relief (Count VI). In the instant matter, Defendant moves to dismiss the Complaint in its entirety. For the reasons set forth below, Defendant’s motion is granted as follows: with respect to Counts I (NJCFA) and II (Common Law Fraud), Plaintiff’s claims regarding the misrepresentation that Clenbutrx is “certified by science” and that Clenbutrx is a “dietary supplement” are DISMISSED WITHOUT PREJUDICE. The remaining fraud allegations —i.e., statements regarding Clenbutrx is the world’s fastest, hardest hitting fat incinerator and authentic synergistic blend of ingredients—are DISMISSED WITH PREJUDICE. In addition, Counts III (Unjust Enrichment) and VI (Injunctive Relief) are DISMISSED WITHOUT PREJUDICE. Lastly, Count IV (Breach of Express Warranty) and Count V (Breach of Implied Warranty) are DISMISSED WITHOUT PREJUDICE.

I. BACKGROUND

In addressing Defendant’s Motion to Dismiss, this Court must accept as true the allegations contained in the Complaint. *See Toys “R” Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 457 (3d Cir.2003); *Dayhoff, Inc. v. H.J. Heinz Co.*, 86 F.3d 1287, 1301 (3d Cir.1996). Thus, the facts recited herein are taken from the Complaint and do not represent this Court’s factual findings.

VPX manufactures, markets and sells a line of “dietary supplements” including Clenbutrx. Compl. ¶ 14. Since 2006¹, *inter alia*, internet advertisements and the product packaging represented and warranted that Clenbutrx contains “Apple Geranium (Pelargonium odorantissimum) (leaves) standardized to 1, 3 Dimethylpentylamine.” *Id.* ¶ 16. In addition, VPX advertises that Clenbutrx is “certified by science, backed by the real world, and proven to give you mind blowing energy” and that its “authentic synergistic blend of ingredients ... leave[s] scientists wondering how amazing this stuff is.” *Id.* ¶ 17. Because of these misrepresentations, Plaintiff purchased Clenbutrx for \$29.99. *Id.* ¶ 36.

¹ The Court notes that in Plaintiff’s opposition brief, he points out that after being served with the Complaint, Defendant removed “Apple Geranium (Pelargonium odorantissimum) (leaves) standardized to 1, 3 dimethylpentylamine” from the ingredients of Clenbutrx, as well as its marketing materials. Pl’s Opp. Br. at 3. This fact was not disputed by Defendant.

*2 On July 18, 2011, Plaintiff filed the instant Complaint against VPX, asserting a violation of the NJCFA, common law fraud, unjust enrichment, and breaches of express and implied warranties. The genesis of Plaintiff's complaint is that Defendant's advertisements and packaging of the dietary supplement, Clenbutrx, contained false and misleading statements which led Plaintiff to purchase such product.² Specifically, Plaintiff alleges that the various representations concerning Clenbutrx induced consumers to believe that they were purchasing a product containing "apple geranium ... [standardized] to 1, 3 Dimethylpentylamine." *Id.* ¶ 18. Contrary to this representation, Plaintiff alleges that, apple geranium, a natural substance, does not normally contain 1, 3 Dimethylpentylamine, which is a synthetic laboratory-produced chemical compound. *Id.* ¶¶ 20–21. In that regard, Plaintiff complains that he was induced into purchasing Clenbutrx, a self proclaimed dietary supplement, when the supplement actually contains a synthetic compound. *Id.* ¶ 26. As a result, Plaintiff avers that Defendant's "misrepresentation[]" that Clenbutrx "is a 'DIETARY SUPPLEMENT' " that contains Apple Geranium has "misled consumers in general and Plaintiff in particular into believing that ... Clenbutrx ... is a dietary supplement, and as a dietary supplement contains *only* dietary ingredients" *Id.* ¶ 28 (emphasis added). In addition, Plaintiff claims that VPX's representations that Clenbutrx is "certified by science, backed by the real world," and that "scientists [are] wondering how amazing this stuff is" are false because "[n]o scientist has ever 'certified' or 'backed' this product's ingredient at issue." *Id.* ¶ 57.

² The language of the allegations in the Complaint, specifically, ¶¶ 18–22, are subject to varying interpretations. However, in light of the nature of Plaintiff's claims, the Court will construe these allegations in the manner set forth in this Opinion.

On or about August 9, 2011, Defendant filed the instant Motion to Dismiss, contending that: (1) Plaintiff did not plead the fraud claims with sufficient particularity; (2) the labeling of Clenbutrx as a "dietary supplement" was mandated by federal law; (3) the alleged misleading statements on Clenbutrx's website are puffery; and (4) Plaintiff did not suffer an ascertainable loss. Def's Mot. at 6–11. In addition, Defendant contends that Plaintiff's unjust enrichment and warranty claims fail as a matter of law.

On or about September 28, 2011, Plaintiff filed opposition to Defendant's Motion to Dismiss. Defendant filed a Reply Brief on or about October 17, 2010.

II. STANDARD OF REVIEW

The Federal Rules of Civil Procedure provide that a complaint "shall contain (1) a short and plain statement of the grounds upon which the court's jurisdiction depends ... (2) a short and plain statement of the claim showing that the pleader is entitled to relief, and (3) a demand for judgment for the relief the pleader seeks." [Fed.R.Civ.P. 8\(a\)](#). The purpose of a complaint is "to inform the opposing party and the court of the nature of the claims and defenses being asserted by the pleader and, in the case of an affirmative pleading, the relief being demanded." [Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1182 \(3d ed.2004\)](#).

*3 When reviewing a motion to dismiss, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." [Phillips v. County of Allegheny](#), 515 F.3d 224, 233 (3d Cir.2008) (citation and quotations omitted). In [Bell Atlantic Corporation v. Twombly](#), 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in [Conley v. Gibson](#), 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Id.* at 561 (quoting [Conley](#), 355 U.S. at 45–46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." *Id.* at 555. As the Third Circuit has stated, "[t]he Supreme Court's *Twombly* formulation of the pleading standard can be summed up thus: 'stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest 'the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of 'the necessary element'.'" [Phillips](#), 515 F.3d at 234 (quoting [Twombly](#), 550 U.S. at 556).

In affirming that *Twombly* standards apply to all motions to dismiss, the Supreme Court recently explained the following principles. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." [Ashcroft v. Iqbal](#), 556 U.S. 662, —, 129

S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210–11 (3d Cir.2009). “Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.” *Id.* at 1950. The plausibility standard requires that “the plaintiff plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged” and demands “more than a sheer possibility that a defendant has acted unlawfully.” *Iqbal*, 129 S.Ct. At 1949 (quoting *Twombly*, 550 U.S. at 556). Ultimately, “a complaint must do more than allege the plaintiff’s entitlement to relief. A complaint has to ‘show’ such an entitlement with its facts.” *Fowler*, 578 F.3d at 211. In evaluating a motion to dismiss, a court may consider only the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the complainant’s claims are based upon these documents. *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir.1993).

III. DISCUSSION

A. NJCFA and Common Law Fraud

*4 The NJCFA provides in relevant part:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

N.J.S.A. § 56:8–2.

The term “person” as used in the NJCFA includes, *inter alia*, natural persons, partnerships, corporations, companies, trusts, business entities and associations. N.J.S.A. § 56:8–1(d).

To state a *prima facie* case under the NJCFA, a plaintiff must sufficiently plead three elements: (1) unlawful conduct by the defendant; (2) an ascertainable loss by the plaintiff; and (3) a causal connection between the defendant’s unlawful conduct and the plaintiff’s ascertainable loss. *Payan v. GreenPoint Mortg. Funding, Inc.*, 681 F.Supp.2d 564, 572 (D.N.J.2010) (citing *Bosland v. Warnock Dodge, Inc.*, 197 N.J. 543, 964 A.2d 741, 749 (2009)). Unlawful practices under the NJCFA fall into three general categories: affirmative acts, knowing omissions, and regulation violations. *Frederico v. Home Depot*, 507 F.3d at 188 (3d Cir.2007)). Intent to defraud is not necessary to show unlawful conduct by an affirmative act of the defendant, but is an element of unlawful practice by knowing omission of the defendant. See *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 691 A.2d 350 (1997); *Torres–Hernandez v. CVT Prepaid Solutions, Inc.*, No. 08–1057, 2008 WL 5381227, at *6 (D.N.J. Dec.17, 2008).

Moreover, it is well-established that claims under the NJCFA must also meet the heightened pleading requirements of Fed.R.Civ.P. 9(b). See, e.g., *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir.2007); *Arcand v. Brother Intern. Corp.*, 673 F.Supp.2d 282 (D.N.J.2009). Pursuant to that rule, a plaintiff alleging fraud must state the circumstances of the alleged fraud with particularity. Fed.R.Civ.P. 9(b). In order to satisfy this heightened pleading standard, a plaintiff “must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the ‘precise misconduct with which [it is] charged.’ Specifically, the plaintiff must plead or allege the “date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.” *Frederico*, 507 F.3 at 200. Indeed, the Third Circuit has advised that, at a minimum, a plaintiff must support allegations of fraud with all the essential factual background that would accompany “the first paragraph of any newspaper story”—that is, the ‘who, what, when, where and how’ of the events at issue.” *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276–77 (3d Cir.2006) (citations omitted) abrogated on other grounds by *Tellabs, Inc. v. Makor Issues & Rights, L.T.D.*, 551 U.S. 308, 322–23, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007). Moreover, a complaint sounding in fraud must do more than assert generalized facts, it must allege facts specific to the plaintiff. *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658–59 (3d Cir.1998) abrogated on other grounds by *Rotella v. Wood*, 528 U.S. 549, 120 S.Ct. 1075, 145 L.Ed.2d 1047 (2000) (where the complaint failed to allege “what actually happened to either” of the plaintiffs, the complaint

did not plead “fraud with the specificity required by Rule 9(b).”).

*5 In addition, Plaintiff’s common law fraud must also be pled with specificity. To plead a fraud claim, a plaintiff must allege “(1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resultant damages.” *Banco Popular North America v. Gandi*, 184 N.J. 161, 172–73, 876 A.2d 253 (2005).

1. Unlawful Conduct

Plaintiff’s NJCFA claim must contain specific allegations of Defendants’ unlawful conduct, subject to the heightened pleading requirements of Rule 9(b). To constitute an affirmative misrepresentation under the NJCFA, the statement must be: (1) material to the transaction; (2) a statement of fact; (3) found to be false; (4) and calculated to induce the buyer to make the purchase. *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 607, 691 A.2d 350, 366 (1997). “A statement of fact is material if: (a) a reasonable person would attach importance to its existence in determining a choice of action ...; or (b) the maker of the representation knows or has reason to know that its recipient regards or is likely to regard the matter as important in determining his choice of action, although a reasonable man would not so regard it.” *Ji v. Palmer*, 333 N.J.Super. 451, 755 A.2d 1221, 1228 (N.J.App.Div.2000) (quoting *Restatement (Second) of Torts* § 538(2)).

In the Complaint, Plaintiff alleges that VPX marketed Clenbutrx as a dietary supplement, and that this advertising was misleading because the product did not contain only dietary ingredients. In addition, Plaintiff contends that the nutrition label on the product touted that the product contains “apple geranium ... [standardized] to 1, 3 Dimethylpentylamine”; however, Plaintiff contends that contrary to the representation on the label, apple geranium, a natural dietary ingredient, contained 1, 3 Dimethylpentylamine, which is a synthetic compound. Finally, Plaintiff argues that Defendant made false and misleading representations concerning Clenbutrx including that the product was “the world’s fastest hardest hitting fat incinerator,” that the product was “certified by science, backed by the real world, and proven to give you mind blowing energy,” and that its “authentic synergistic blend of ingredients ... leave[s] scientists wondering how amazing this stuff is.” In response, Defendant argues that Plaintiff cannot establish a violation of the NJCFA for three separate

reasons: (1) there was no unlawful conduct by Defendant because the labeling of Clenbutrx as a “dietary supplement” was mandated by federal law; (2) the alleged misleading statements on Clenbutrx’s website are puffery; and (3) Plaintiff did not suffer an ascertainable loss.

The Court will separately consider each of the alleged misrepresentations.

i. The Labeling of Clenbutrx as a “Dietary Supplement”

As discussed above, in the Complaint, Plaintiff alleges that Defendant’s labeling of Clenbutrx as a “dietary supplement” is actionable under the NJCFA. Specifically, Plaintiff contends that Defendant affirmatively misrepresented Clenbutrx as a “dietary supplement” because the product does not contain “only dietary ingredients.” Compl. ¶ 26. In other words, Plaintiff appears to allege that because apple geranium contains 1, 3, Dimethylpentylamine, it was improper to label Clenbutrx as a dietary supplement. Plaintiff’s allegations fall short of stating a viable claim.

*6 Pursuant to 21 U.S.C. § 321(ff)(1), a dietary supplement is “a product (other than tobacco) intended to supplement the diet that bears or contains *one or more* of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in (A), (B), (C), (D), or (E).” 21 U.S.C. § 321(ff)(1) (emphasis added); see *GNC Franchising LLC v. Sala*, No. 06-191, 2006 U.S. Dist. LEXIS 11320, at *11-13 (W.D.Pa. Mar. 20, 2006). Significantly, a substance’s intended use is relevant to deciding whether the product is a dietary supplement. See 21 U.S.C. § 321(ff)(1); see *United States v. Lane Labs–USA, Inc.*, 324 F.Supp.2d 547, 564 (D.N.J.2004).

Here, responding to Plaintiff’s allegations, Defendants argue that “Clenbutrx contains dietary ingredients, including other botanicals, [thus] the labeling of this product as a ‘dietary supplement’ was entirely proper. Def’s Rep. Br. at 5. At the motion to dismiss stage, the Court cannot credit Defendant’s assertion regarding what types of ingredient are contained in Clenbutrx. However, even taking the Complaint as true, Plaintiff’s allegations fail to state a claim. Plaintiff has failed to allege that there is *no* dietary ingredient listed on the Clenbutrx label; instead, Plaintiff alleges only that because apple geranium, a natural ingredient, contains 1, 3,

Dimethylpentylamine, it was improper to label Clenbutrx as a dietary supplement. This lone allegation does not come close to state a claim under the statutory scheme of § 321(f). Rather, the statute specifically provides for the labeling of a product as a “dietary supplement” if the supplement contains *one or more* specified dietary ingredients. See 21 U.S.C. § 321(f)(1). In fact, the statute does not require that *every* ingredient must be a dietary ingredient. In that regard, Plaintiff does not allege that Clenbutrx does not contain other botanicals, or that there are no other dietary ingredients in Clenbutrx. Simply stated, the mere fact that apple geranium in Clenbutrx may not be an herb or a botanical does not necessarily mean that Clenbutrx does not have other dietary ingredients that would qualify it as a dietary supplement. Moreover, Plaintiff has failed to allege that Clenbutrx is not intended to be used as a dietary supplement. Accordingly, the Court finds that Plaintiff’s claim, as it is currently pled, concerning the labeling of Clenbutrx as a dietary supplement is not actionable under the NJCFA. This claim is dismissed without prejudice.

ii. Statements Made on Clenbutrx’s Website

Next, Plaintiff contends that the following separate statements on Defendant’s website constitute affirmative misrepresentations: (1) Clenbutrx is “the world’s fastest, hardest hitting fat incinerator”; (2) Clenbutrx is “certified by science, backed by the real world, and proven to give you mind-blowing energy”; and (3) Clenbutrx’s “authentic synergistic blend of ingredients ... leave[s] scientists wondering how amazing this stuff is.” (Compl.¶ 16.) In response, Defendant argues that these statements are not actionable under the NJCFA because they are puffery.

*7 “The NJCFA distinguishes between actionable misrepresentations of fact and ‘puffery.’ *In re Toshiba America HD DVD Marketing and Sales Practices Litigation*, Civ. No. 08-939, 2009 WL 2940081, at *9 (D.N.J. Sept. 11, 2009) (citing *Rodio v. Smith*, 123 N.J. 345, 352, 587 A.2d 621 (1991)) (finding that the slogan “[y]ou’re in good hands with Allstate” was “nothing more than puffery” and as such was not “a deception, false promise, misrepresentation, or any other unlawful practice within the ambit of the Consumer Fraud Act.”) “Advertising that amounts to ‘mere’ puffery is not actionable because no reasonable consumer relies on puffery. The distinguishing characteristics of puffery are vague, highly subjective claims as opposed to specific, detailed factual assertions.” *Id.* at *10, 587 A.2d 621 (quoting *Haskell v. Time, Inc.*, 857 F.Supp. 1392, 1399 (E.D.Cal.1994)); *see, e.g.*, *Hughes v. Panasonic*, Civ. A.

No. 10-846, 2011 WL 2976839, at *35, 36 (D.N.J. July 21, 2011) (holding that Panasonic’s statements about the televisions’ “industry leading black levels and contrast ratios” as well its representations about the television technology’s ability to render images “the way the director intended” and producing “breathtaking” and “vivid” colors are non-actionable puffery). Moreover, “[i]t has been noted in the context of Lanham Act cases that, unlike puffery, ‘false claims that explicitly or implicitly address product attributes of importance to customers and make statements that are measurable by comparative research are not puffery.’ *Bracco Diagnostics, Inc., v. Amersham Health, Inc.*, 627 F.Supp.2d 384, 464 (D.N.J.2009) (citing *Castrol Inc., v. Pennzoil Co.*, 987 F.2d 939, 945-46 (3d Cir.1993) (holding that Pennzoil’s claim of superior engine protection was more than mere puffery because “it is both specific and measurable by comparative research”)). The Court will consider each statement in turn.

Here, Plaintiff argues that the statements that Clenbutrx is “the world’s fastest, hardest hitting fat incinerator” and that Clenbutrx contains an “authentic synergistic blend of ingredients ... [that] leave[s] scientists wondering how amazing this stuff is” are actionable misrepresentations under the NJCFA. The Court does not agree. These statements are the epitome of vague and highly subjective claims of superiority. *See, e.g., In re Toshiba*, 2009 WL 2940081, at *10. While Defendants use the buzz words “authentic” or “scientists,” that is not sufficient to bring the statements out of the realm of puffery because these statements are not making a specific claim as to the product. *See Tatum v. Chrysler Group LLC*, No. 10-4269, 2011 U.S. Dist. LEXIS 32362, at *14, 2011 WL 1253847 (D.N.J. Mar. 28, 2011) (“Absent specific claims as to the braking system, Defendant’s general advertising was puffery”). Indeed, neither of these statements contains a specific or detailed factual assertion upon which a reasonable consumer would rely. *See Angrisani v. Capital Access Network, Inc.*, 175 Fed. Appx. 554, 556 (3d Cir.2006) (“statements that can be categorized as “puffery” or vague and “ill-defined opinions” are not assurances of fact and do not constitute misrepresentations.”) (citation omitted). Rather, such statements are routinely made by companies seeking to gain a competitive advantage in their respective industries, and therefore they are considered puffery. *In re Toshiba*, 2009 U.S. Dist. LEXIS 82833 at *28. As such, the Court holds that these statements do not constitute actionable misrepresentations for purposes of the NJCFA, and Plaintiff is precluded from bringing NJCFA claims based upon those statements of puffery.

*8 On the other hand, the statement that Clenbutrx is “certified by science” is not puffery and thus could be actionable under the NJCFA. Indeed, unlike the above statements, Defendant’s use of the term “certified by science,” transforms a subjective statement that might otherwise be considered puffery, i.e., that the product will “give you mind blowing energy,” into something that appears “both specific and measurable.” *Castrol*, 987 F.2d at 946; *see, e.g.*, *Lieberson v. Johnson & Johnson Consumer Cos.*, No. 10-6196, 2011 U.S. Dist. LEXIS 107596, at *24, 2011 WL 4414214 (D.N.J. Sept. 21, 2011) (product labels touting that the products were “clinically proven to help babies sleep better” was not puffery). Moreover, Plaintiff alleges that no scientist has ever “certified” or “backed” Clenbutrx. Compl. ¶ 57. Thus, the Court finds that the statement that Clenbutrx is “certified by science, backed by the real world, and proven to give you mind blowing energy” is an actionable misrepresentation under the NJCFA.

Thus, the Court will consider the additional prongs required to set forth a claim under the NJCFA regarding the statement that Clenbutrx is “certified by science.”³

³ In the event Plaintiff amends the Complaint on his affirmative misrepresentation claim regarding Clenbutrx’s characterization as a “dietary supplement”—which the Court has dismissed—Plaintiff must be mindful that in order to properly allege a NJCFA claim based on that representation, the allegations must conform to the Court’s rulings on the remainder of the NJCFA elements.

2. **Ascertainable Loss**

Next, Defendant argues that Plaintiff has not pled an ascertainable loss sufficient to establish a cause of action under the NJCFA because he “purchased a dietary supplement manufactured in compliance with the dietary supplement guidelines. Thus, Plaintiff did not suffer a loss in receiving what he paid for.” Def’s Rep. Br. at 6. In response, Plaintiff argues that he suffered an ascertainable loss of \$29.99, i.e., the price he paid for Clenbutrx. The Court agrees that at this juncture, Plaintiff has pled an ascertainable loss.

Under the NJCFA, “[a]n ascertainable loss is a loss that is ‘quantifiable or measurable’; it is not ‘hypothetical or illusory.’” *Lee v. Carter-Reed Co., L.L.C.*, 203 N.J. 496, 522 (2010) (quoting *Thiedemann v. Mercedes-Benz USA, LLC*, 183 N.J. 234, 248, 872 A.2d 783 (2005)). There

are at least three recognized theories of ascertainable loss that may apply to a NJCFA claim. In cases involving product misrepresentation, “either out-of-pocket loss or a demonstration of loss in value will suffice to meet the ascertainable loss hurdle....” *Thiedemann*, 872 A.2d at 792. The “out-of-pocket” theory may include the purchase price of a misrepresented product if the purchasers did not receive a refund and the seller’s misrepresentations rendered the product essentially worthless. *See Lee*, 2010 N.J. LEXIS 951, at *51–52, 2010 WL 3781595. A “loss-in-value” theory is based on the quantifiable difference in value between the merchandise as advertised and the merchandise as delivered. *Thiedemann*, 872 A.2d at 792 (stating that an expert may employ a “market conditions” approach to product value to determine ascertainable loss). Under the third theory, an “ascertainable loss” can include a nominal overcharge for which the plaintiffs have not made a “pre-suit demand for a refund.” *Bosland*, 964 A.2d at 751.

*9 Here, it is clear that Plaintiff is asserting an “out-of-pocket” theory of loss; specifically, Plaintiff alleges that he “suffered an ascertainable loss of monies, including, but not necessarily limited to the purchase price of the Liquid Clenbutrx Hardcore [he] purchased[.]” In addition, Plaintiff contends that he “would not have purchased” the product but for Defendant’s misrepresentations. Compl. ¶ 38. The Court notes, however, that the ascertainable loss would only relate to the misrepresentations regarding Clenbutrx as a dietary supplement and the statement that Clenbutrx is “certified by science.”

Accordingly, the Court finds that Plaintiff has sufficiently pled ascertainable loss.

3. **Causation**

Finally, Defendant argues that Plaintiff has not established the third prong of a NJCFA claim—i.e. a causal relationship between the alleged unlawful conduct and Plaintiff’s ascertainable loss. Indeed, it is well-established that “[c]ausation under the CFA is not the equivalent of reliance.” *Lee*, 203 N.J. at 522; *see also Int’l Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc.*, 192 N.J. 372, 929 A.2d 1076 (2007) (holding that the CFA “essentially replaces reliance, an element of proof traditional to any fraud claim, with the requirement that plaintiff prove an ascertainable loss.”) “To establish causation, a consumer merely needs to demonstrate that he or she suffered an ascertainable loss ‘as a result of’ the unlawful practice.” *Id.*

However, in the context of advertisements, causation is particularly crucial under the Rule 9(b) heightened pleading requirements. In that regard, Plaintiff, here, must allege how his ascertainable loss was attributable to the unlawful conduct. In other words, Plaintiff must allege where and when he saw the advertisement which contained the alleged misrepresentation. *See, e.g., Gross v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 303 N.J.Super. 336, 346, 696 A.2d 793 (App.Div.1997) (CFA class could only include persons who “saw the challenged advertisements” and “would not have purchased the Pepcid but for the challenged advertisements.”); *Solo v. Bed Bath & Beyond, Co.*, No. 06-1908, 2007 U.S. Dist. LEXIS, at *12 (D.N.J. Apr. 26, 2007); *Franulovic v. The Coca-Cola Company*, No. 07-539, 2007 U.S. Dist. LEXIS, at *24, 2007 WL 3166953 (D.N.J. Oct.25, 2007) (plaintiff failed to “allege that she purchased Enviga because of a certain misleading ad, or that she purchased the prescribed amount of Enviga and did not enjoy the advertised effects. Melfi also does not allege that other consumers actually purchased the beverage because of Defendants’ advertising, or that they did not get the advertised results. Instead, Melfi’s claims generally state that Enviga’s marketing was false and misleading, without alleging that this false advertising caused her a quantifiable loss.”).

Plaintiff has fail to so plead here. Instead, Plaintiff, in a broad-brush fashion, alleges that he purchased Clenbutrx “upon being induced, by Defendant VPX’s packaging and promotional materials and Internet advertising” Compl. ¶ 26. While Plaintiff lists various websites wherein VPX advertised Clenbutrx, Plaintiff fails to identify any specific advertisement he viewed, where he viewed it, how he was misled by these advertisements and how these advertisements caused his injuries. In other words, the Complaint fails to identify which, if any, of the promotional or marketing materials were viewed by Plaintiff, and if they were, when these materials were viewed and how they induced Plaintiff to purchase Clenbutrx. More simply stated, Plaintiffs have failed to allege any specific facts establishing a connection between the alleged conduct of Defendants and the alleged injury claimed. Moreover, as a corollary issue, Plaintiff also fails to allege where he purchased Clenbutrx, i.e., a store, by mail, or on the internet. This is important because according to Plaintiff’s allegations, he was induced by Defendants’ online advertisement into purchasing the supplement. At the same time, Plaintiff also alleges that he was induced by the packaging of Clenbutrx, but he does not specify where he observed the packaging. Absent any explanation of the connection between Plaintiff’s alleged damages and the

wrongful conduct of VPX, Plaintiff’s NJCFA claim also fails on this basis.

***10** In light of the above analysis, the Court dismisses without prejudice Plaintiff’s NJCFA claim regarding the alleged misrepresentation that Clenbutrx is a “dietary supplement” and the statement that Clenbutrx is “certified by science.” The remaining allegations related to Plaintiff’s NJCFA claim are dismissed with prejudice.

Finally, Plaintiff’s common law fraud claim is dismissed without prejudice for the same reasons stated above.

C. Plaintiff’s Unjust Enrichment Claim

Under the set of facts Plaintiff has alleged, Plaintiff has not stated a claim for unjust enrichment. “To establish unjust enrichment, the plaintiff must show both that defendant received a benefit and that retention of that benefit without payment would be unjust.” *VRG Corp. v. GKN Realty Corp.*, 135 N.J. 539, 554, 641 A.2d 519 (1994). Specifically, “the unjust enrichment doctrine requires that plaintiff show that it expected remuneration from the defendant at the time if performed or conferred a benefit on defendant and that the failure of remuneration enriched defendant beyond its contractual rights.” *Id.* Importantly, in New Jersey, a claim for unjust enrichment requires a direct relationship between the parties. *See, e.g., Cooper v. Samsung Elecs. Am. Inc.*, No. 07-3853, 2008 U.S. Dist. LEXIS 75810, 2008 WL 4513924 (D.N.J.2008); *see also Premier Pork L.L.C. v. Westin Inc.*, No. 07-1661, 2008 U.S. Dist. LEXIS 20532, 2008 WL 724352, at *14 (D.N.J.2008) (“quasi contract claims involve either some direct relationship between the parties or a mistake on the part of the person conferring the benefit ...”); *Callano v. Oakwood Park Homes Corp.*, 91 N.J.Super. 105, 109, 219 A.2d 332 (App.Div.1966) (citing importance of either a direct relationship or a mistake in quasi-contract). For example, in *Cooper*, the court held that although plaintiff alleged that the manufacturer was unjustly enriched through the purchase of a television, plaintiff had not conferred a direct benefit on the manufacturer since the purchase was made through a retailer. As a result, the court dismissed plaintiff’s unjust enrichment claim.

Applied here, the Court finds that Plaintiff has not sufficiently alleged a claim for unjust enrichment. Indeed, as in *Cooper*, Plaintiff has not alleged where he purchased Clenbutrx, i.e., whether he purchased it directly from Defendant or if he purchased the product through a retail establishment, online or otherwise. As a result, the Court is unable to determine

whether there is a direct relationship between the parties such that Plaintiff can establish that he conferred a benefit upon Defendant for purposes of an unjust enrichment claim. Thus, the Court will dismiss Plaintiff's unjust enrichment claim without prejudice.

D. Warranty Claims

1. Pre-litigation Notice

Plaintiff asserts claims of breach of express warranty and breach of implied warranty of merchantability. However, fatal to both claims is the lack of allegations involving pre-litigation notice. New Jersey has adopted the Uniform Commercial Code's ("UCC") notice requirement for an express warranty claim. *Luppino v. Mercedes-Benz USA, LLC*, No. 09-5582, 2011 U.S. Dist. LEXIS 65495, at *7, 2011 WL 2470625 (D.N.J. Jun. 20, 2011); *Joc, Inc. v. Exxonmobil Oil Corp.*, No. 08-5344, 2010 WL 1380750, at *4 (D.N.J. Apr. 1, 2010); *Slack v. Suburban Propane Partners, L.P.*, No. 10-2548, 2010 WL 5392845, at *4-5 (D.N.J. Dec. 22, 2010). It provides: "Where a tender has been accepted ... the buyer must within a reasonable time after [s]he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." N.J.S.A. 12A:2-607(3)(a). Based upon the language, this statutory notice is a "condition precedent to filing any suit for breach of warranty." *Joc*, 2010 WL 1380750 at *4. A similar requirement is needed for a breach of implied warranty. See *C.F. Seabrook Co. v. Beck*, 174 N.J.Super. 577, 593, 417 A.2d 89 (App.Div.1980) ("New Jersey law on sales requires notice as a prerequisite to the buyer's assertion that the seller breached an implied warranty of merchantability." (citing *Johnson v. Hoffman*, 7 N.J. 123, 131, 132, 80 A.2d 624 (1951)).

*11 Here, Plaintiff has failed to plead that he provided the pre-litigation notice of breach. More importantly, Plaintiff offers no excuse or explanation for his failure to do so. Accordingly, because Plaintiff has failed to allege that the condition precedent has been met—sending a pre-litigation notice—Plaintiff's express and implied warranty claims necessarily fail. See *Luppino*, 2011 U.S. Dist. LEXIS 65495 at *7 ("At no time has any court in this district or in the state of New Jersey found that a buyer is not required to provide a direct seller with pre-suit notice in an action for express breach of warranty. Thus, Stern and Casiero's admission that they have failed to provide notice to Defendant proves fatal to their breach of express warranty claims.").

However, regardless of notice, both warranty claims are also inadequately pled and thus subject to dismissal. The Court turns to those analyses.

2. Breach of Express Warranty

In the Complaint, Plaintiff alleges that by labeling Clenbutrx as a "dietary supplement," Defendant expressly warranted that the product contained only dietary ingredients including "Apple Geranium ... standardized to 1, 3 Dimethylpentylamine." Compl. ¶¶ 69, 71. In its Motion to Dismiss, Defendant argues that Plaintiff did not adequately plead his claim for breach of express warranty. Specifically, Defendant argues that Clenbutrx "conforms to all affirmations, promises or descriptions made by VPX," and that Clenbutrx "contains all of the ingredients on the product's label, which include components, in addition to apple geranium, that qualify it as a dietary supplement." Def's Br. at 14-15.

Under New Jersey law, a breach of express warranty claim has four elements: "(1) a contract between the parties; (2) a breach of that contract; (3) damages flowing therefrom; and (4) that the party stating the claim performed its own contractual obligations." *Frederico*, 507 F.3d at 203. Moreover, courts in this Circuit have held that an advertisement may create an express warranty. See, e.g., *Cipollone v. Liggett Group, Inc.*, 893 F.2d 541, 575-76 (3d Cir.1990) rev'd in part on other grounds 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (concluding that cigarette advertisements representing that the cigarettes were safe could constitute an express warranty); *Elias v. Ungar's Food Products, Inc.*, 252 F.R.D. 233, 252 (D.N.J.2008) (packaging statements regarding fat and caloric content created express warranty). For example, in Elias, plaintiff alleged that descriptions on the packages of five products about fat and caloric content did not conform with the product because the product contained substantially more calories and fat than described. As a result, plaintiffs argued that the express warranty concerning the lower caloric and fat content had been breached. *Id.* at 251. The court agreed and held that the express warranty appeared to be breached. *Id.*

*12 In the instant matter, Plaintiff argues that by labeling Clenbutrx as a "dietary supplement," Defendant warranted that the product contained only dietary ingredients. As discussed above, 21 U.S.C. § 321(ff)(1) provides that a product may be labeled as a dietary supplement if it contains one or more dietary ingredients. Thus, even if Defendant's labeling of Clenbutrx as a "dietary supplement" created an

express warranty between the parties, because Plaintiff does not allege that the product does not contain any “dietary ingredients” as defined by [21 U.S.C. § 321\(f\)\(1\)](#), Plaintiff has not stated a claim for breach of that warranty. Simply put, taking Plaintiff’s Complaint as true, even if apple geranium is not a dietary ingredient, Plaintiff has failed to allege that there are no other dietary ingredients, or equivalent, contained in Clenbutrix. Without those allegations, Plaintiff has not sufficiently alleged a breach of an express warranty. Accordingly, this claim is dismissed without prejudice.

3. Breach of Implied Warranty of Merchantability

In addition, Plaintiff alleges that VPX breached the implied warranty of merchantability because Clenbutrx was “not adequately packaged, labeled, sold, promoted, or fit for the ordinary purposes” as a dietary supplement. Compl. ¶¶ 75, 78. Specifically, Plaintiff appears to argue that Defendant “impliedly warranted that the product is composed entirely of dietary ingredients, that 1, 3 dimethylpentylamine is found in apple geranium, and that therefore the product is safe.” Compl. ¶ 75.⁴

⁴ Plaintiff also asserts that Defendant breached an implied warranty by failing to publish its “money back” guarantee on the Clenbutrx packaging materials; the guarantee was only published on its website. As stated above, a breach of implied warranty concerns the merchantability of the product; however, nothing in Plaintiff’s allegations regarding the money back guarantee concerns the product’s fitness for its ordinary purpose. Thus, Plaintiff’s allegations in this context cannot form a legal basis for a breach of implied warranty claim. Moreover, even if this were a sufficient basis, Plaintiff has not cited any authority that requires a manufacturer or seller to offer a money back guarantee as a matter of law, let alone requiring companies to advertise that guarantee in a particular way. Accordingly, the Court will dismiss these allegations with prejudice.

Pursuant to [N.J.S.A. 12A:2-314](#), “a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind ...” [N.J.S.A. 12A:2-314](#). “‘Merchantability’ requires that a product conform to its ordinary and intended use.” [Hughes, 2011 WL 2976839 at *22](#) (quoting [Berenblat v. Apple, Inc., 2009 WL 2591366, at *2](#) (N.D.Cal. Aug.21, 2009)). “In order for the implied warranty of merchantability

to be breached, the product at issue must have been defective or not fit for the ordinary purpose for which it was intended.” *In re In re Toshiba Am. HD DVD Marketing and Sales Practices Litigation* at *16. “The implied warranty of merchantability does not ‘impose a general requirement that goods precisely fulfill the expectation of the buyer. Instead, it provides for a minimum level of quality.’” [Hughes, 2011 WL 2976839, at *22](#) (quoting [Berenblat](#) at *3). Indeed, the warranty of merchantability “‘simply means that the thing sold is reasonably fit for the general purpose for which it is manufactured and sold.’” [Ferrari v. American Honda Motor Co., Inc., 2009 WL 211702, at *3](#) (N.J.App.Div. Jan. 30, 2009) (quoting [Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 370, 161 A.2d 69 \(1960\)](#) (emphasis added)).

In this instant matter, Plaintiff does not dispute that Clenbutrx is sold for the ordinary purpose as a dietary supplement. *See, e.g.*, Compl. ¶ 76 (“Defendant made such implied warranties knowing that the ordinary purpose for which Liquid Clenbutrx Hardcore was to be used was as a dietary supplement.”). Instead, with regard to the implied warranty claim, Plaintiff alleges, at most, that the product contains ingredients other than dietary ingredients, and therefore, the product is unsafe. However, Plaintiff has proffered nothing by way of pleadings to support its assertion that a dietary supplement is not “merchantable” if it contains components other than dietary ingredients or that Clenbutrx is somehow unsafe. Similarly, Plaintiff has entirely failed to allege or explain why the inclusion of “apple geranium standardized to 1, 3 Dimethylpentylamine” renders Clenbutrx unfit for the purpose of being a dietary supplement. Thus, the Court will dismiss Plaintiff’s claim for breach of the implied warranty of merchantability without prejudice.

E. Plaintiff’s Claim for Injunctive Relief

***13** Finally, Plaintiff asserts a cause of action for injunctive relief, arguing that Defendant should be enjoined from continuing its marketing and sale of Clenbutrx. Compl. ¶ 87. In response, Defendant contends that injunctive relief is not a recognized cause of action and should be dismissed. In addition, Defendant contends that even if the Court recognized this cause of action, since VPX has changed its labeling and advertisements, this cause of action is moot. Def’s Rep. Br. at 15.

Initially, the Court notes that at least one court in this district has held that injunctive relief is not separate cause of action. *See Smajlaj, 2011 WL 1086764, at *2* (“Plaintiffs also seek injunctive relief, which they mistakenly characterize

as a cause of action.”). Moreover, the Court finds that in this matter, Plaintiff’s claim for injunctive relief appears to be expressly tied to his fraud claims; specifically, Plaintiff alleges that Defendant’s actions “of marketing, advertising, promoting, distributing, and selling” Clenbutrx “continue to deceive” the public. Compl. ¶ 85. Thus, Plaintiff asks this Court to enjoin Defendant from “continuing their marketing, advertisement, promotion, distribution, and sale” of Clenbutrx. Compl. ¶ 87. Because the Court has already dismissed Plaintiff’s fraud claims, and in the apparent absence of any other cause of action connected to Plaintiff’s claim for injunctive relief, the Court will dismiss Plaintiff’s cause of action for injunctive relief without prejudice. Importantly, however, in the event Plaintiff re-pleads his fraud claims, he must request an injunction as a part of the relief, not as a separate cause of action.

IV. CONCLUSION

For the foregoing reasons, Defendants’ Motion to Dismiss is GRANTED. Specifically, with respect to Counts I (NJCFA) and II (Common Law Fraud), Plaintiff’s claims regarding the misrepresentation that Clenbutrx is “certified by science” and that Clenbutrx is a “dietary supplement” are DISMISSED WITHOUT PREJUDICE. The remaining fraud allegations—i.e., statements regarding Clenbutrx as the world’s fastest, hardest hitting fat incinerator and authentic synergistic blend of ingredients—are DISMISSED WITH PREJUDICE. In addition, Counts III (Unjust Enrichment) and VI (Injunctive Relief) are DISMISSED WITHOUT PREJUDICE. Moreover, with respect to Count IV (Breach of Express Warranty) and Count V (Breach of Implied Warranty) are DISMISSED WITHOUT PREJUDICE. An order will be entered consistent with this Opinion.

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TAB 22

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NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Harold M. HOFFMAN, individually and on behalf of those similarly situated, Plaintiff,

v.

NUTRACEUTICAL CORP., Defendant.

Civil Action No. 12-5803 (ES).

June 10, 2013.

Attorneys and Law Firms

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OPINION

SALAS, District Judge.

I. INTRODUCTION

*1 Pending before this Court is Nutraceutical Corp.'s ("Defendant") Motion to Dismiss Harold M. Hoffman's ("Plaintiff") Complaint. (D.E. No. 10, Brief in Support of Motion to Dismiss Plaintiff's Complaint ("Br.")). The motion is unopposed. The Court has reviewed the submissions and decides the motion without oral argument pursuant to Fed.R.Civ.P. 78(b). For the following reasons, the Court GRANTS the motion without prejudice.

II. BACKGROUND

On August 9, 2012, Plaintiff, individually and on behalf of those similarly situated, filed a complaint against Defendant in the Superior Court of New Jersey, Bergen County. (D.E. No. 1, Complaint ("Compl.")). On September 14, 2012, Defendant removed the state court case to this District (D.E.

No. 1, Notice of Removal ("Removal").¹

¹ On September 21, 2012, Plaintiff filed a motion to remand to state court. (D.E. No. 4). The motion was denied by Judge Mannion via Report & Recommendation ("R & R") on January 24, 2013.

(D.E. No. 20). Plaintiff subsequently objected to Judge Mannion's decision exercising jurisdiction on January 27, 2013. (D.E. No. 21). Judge Salas adopted Judge Mannion's R & R and overruled Plaintiff's objection on March 8, 2013. (D.E. No. 25).

In the Complaint, Plaintiff alleges that Defendant advertised KAL Glucosamine Chondroitin MSM (the "product") as "pure, unadulterated and of the highest quality." (Compl.12). Plaintiff claims that despite the express promise that "[n]o ingredient other than those listed on the label have been added to this product," Defendant's product was "contaminated by 1.7 micrograms of lead per daily use." (*Id.* at 4). Next, Plaintiff claims that he and other members of the putative class relied on the express representations with respect to purity of the product and made the purchase of the product in reliance thereof. (*Id.* at 5-6). Accordingly, Plaintiff argues that Defendant's conduct violates the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2, and constitutes: an unconscionable commercial practice (Count I); deception (Count II); fraud (Count III); false pretense, false promise and/or misrepresentation (Count IV); and knowing concealment, suppression and/or omission of material facts (Count V). In addition, Plaintiff raises the following claims: common-law fraud (Count VI); unjust enrichment (Count VII); breach of express warranty (Count VIII); and breach of implied warranty of merchantability (Count IX). (Compl.14-18).

In response, Defendant moves to dismiss the above counts pursuant to Fed.R.Civ.P. 12(b)(6) because Plaintiff does not state any claim upon which relief may be granted. (Br.2). Specifically, Plaintiff fails to "allege that he was injured by the Product or the alleged lead therein, nor could he as he never claims to have even used the Product." Nor does Plaintiff "make any allegations regarding the Product's performance or efficacy, again having never used the Product." (*Id.* at 5).²

² Defendant also seeks to disqualify Plaintiff as class counsel. The Court need not address the issue in this Fed.R.Civ.P. 12(b) (6) motion.

III. ANALYSIS

A. Legal Standard

For a complaint to survive dismissal, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal*,

556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). In determining the sufficiency of a complaint, the Court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the non-moving party. See *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir.2008). But, “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions[;][t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Iqbal*, 556 U.S. at 678.

B. Plaintiff's Consumer Fraud Act (“CFA”) Claims (Counts I–V)

*2 Plaintiff claims that “[t]he product delivered by Defendant to [P]laintiff and members of the putative class misrepresented the safety, quality, constituent ingredients and purity of defendant's product. Indeed, the spoiled and contaminated product delivered by Defendant to consumers, lacked the purity and beneficial qualities promised by Defendant.” (Compl.6). Defendant contends that Plaintiff's CFA claims must be dismissed because Plaintiff fails to show damages in connection thereto. (Br.15). The Court agrees.

To state a cause of action under the CFA, plaintiff must allege: “(1) an unlawful practice by the defendants; (2) an ascertainable loss by plaintiff; and (3) a causal nexus between the first two elements—defendants' allegedly unlawful behavior and the plaintiff's ascertainable loss.” *Parker v. Howmedica Osteonics Corp.*, No. 07-02400, 2008 WL 141628, at *2 (D.N.J. Jan.14, 2008) (citing *N.J. Citizen Action v. Schering-Plough Corp.*, 367 N.J.Super. 8, 842 A.2d 174, 176 (N.J.Super.Ct.App.Div.2003)).

First, plaintiff must allege an unlawful practice. An unlawful practice “typically involves an affirmative act of fraud and can arise from an affirmative act, an omission, or a violation of an administrative regulation.” *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F.Supp.2d 496, 501 (D.N.J.2006). “[N]ot just ‘any erroneous statement’ will constitute a misrepresentation prohibited” under the CFA. *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 607, 691 A.2d 350 (1997). “The misrepresentation has to be one which is material to the transaction and which is a statement of fact, found to be false, made to induce the buyer to make the purchase.” *Id.*

Next, plaintiff must allege an ascertainable loss. Although the CFA does not define “ascertainable loss,” courts have interpreted it as a “cognizable and calculable claim of loss due to the alleged CFA violation.” *Solo v. Bed, Bath & Beyond, Inc.*, No. 06-1908, 2007 WL 1237825, at *3 (D.N.J. Apr. 26, 2007) (citing *Thiedmann v. Mercedes-Benz USA, LLC*, 183 N.J. 234, 249, 872 A.2d 783 (2005)); *Hoffman v. Hampshire Labs, Inc.*, 405 405 N.J.Super. 105, 963 A.2d 849, 854 (N.J.Super.Ct.App.Div.2009). To properly plead an ascertainable loss, plaintiff must allege facts showing “either an out-of-pocket loss or a demonstration of loss in value.” *Dist. 1199P Health and Welfare Plan v. Janssen, L.P.*, 784 F.Supp.2d 508, 530 (D.N.J.2011) (citing *Thiedmann*, 183 N.J. at 248, 872 A.2d 783). This requirement to show a demonstration of a loss in value includes a benefit-of-the-bargain theory that “requires nothing more than that the consumer was misled into buying a product that was ultimately worth less to the consumer than the product he was promised. *Smajlaj v. Campbell Soup Co.*, 782 F.Supp.2d 84, 99 (D.N.J.2011); *Henderson v. Hertz Corp.*, No. 6937-03, 2005 WL 4127090, at *7-8 (N.J.Super.Ct.App.Div.2005).

Finally, plaintiff must show a causal nexus between the misrepresentation or concealment of the material fact by defendant and the loss suffered by any person. *Dewey v. Volkswagen AG*, 558 F.Supp.2d 505, 526 (D.N.J.2008). Here, Plaintiff failed to make the necessary three-part showing under the CFA. Specifically, Plaintiff failed to show that Defendant's alleged CFA violation caused Plaintiff's “ascertainable loss.” Plaintiff merely alleged that some of Defendant's product contained 1.7 micrograms of lead in it. Even under a benefit-of the-bargain theory of damages, Plaintiff failed to show that the alleged lead in Defendant's product caused the product to be worth less than was promised. Plaintiff failed to show that the product he used actually contained lead. Moreover, Plaintiff failed to establish that the presence of 1.7 micrograms of lead in the product constituted a misrepresentation that is contrary to the product being “pure, unadulterated and of the highest quality.”³ Because Plaintiff failed to make the requisite showing under the CFA, Plaintiff's CFA claims are dismissed.

³ On the contrary, Defendant notes that the recommended daily intake of lead is 75 micrograms, or 44 times the amount found in the product at issue. (Br.5).

C. Plaintiff's Common Law Fraud Claim (Count VI)

*3 Plaintiff avers that “Defendant, in the advertisement, marketing and sale of the [product], deliberately and knowingly engaged in concealment, suppression and/or omission of material facts with the intent that others, including members of the plaintiff-class, rely upon same, and, upon information and belief, members of the class did justifiably rely upon same to their detriment.” (Compl.14). Such conduct, according to Plaintiff, constitutes common-law fraud. (*Id.* at 15). Defendant disagrees and argues that Plaintiff’s common-law fraud claim must be dismissed because Plaintiff “failed to sufficiently plead damages resulting from the alleged trace amount of lead in the [p]roduct.” (Br.19).

To properly plead common-law fraud in New Jersey, plaintiff must show: “(1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages.” *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 610, 691 A.2d 350 (1997) (citing *Jewish Ctr. of Sussex Cnty. v. Whale*, 86 N.J. 619, 624–25, 432 A.2d 521 (1981)).

Here, Plaintiff failed to identify the resulting damages, a requisite showing to properly plead common law fraud. Significantly, Plaintiff does not even allege that the product that he personally purchased, and used, contained lead. Consequently, the Court dismisses Plaintiff’s claim of common-law fraud.

D. Plaintiff’s Breach of Unjust Enrichment Claim (Count VII)

Plaintiff states that “as a result of [Defendant’s] false and deceptive conduct ... [Defendant] became indebted to class members for the sums paid by class members ... for purchase of a misrepresented product.” (Compl.16). And retention of said sums “without reimbursement, would result in the unlawful, unjust and inequitable enrichment.” (*Id.*). Defendant disagrees and argues that because Plaintiff “failed to plead that the [p]roduct failed to function as advertised or that he was injured by the [p]roduct ... there was nothing unjust about [Defendant’s] accepting and retaining money in exchange for delivering the [p]roduct to [Plaintiff].” (Br.20).

The doctrine of unjust enrichment “rests on the equitable principle that a person shall not be allowed to enrich himself unjustly at the expense of another.” *Assoc. Comm. Corp. v. Wallia*, 211 N.J.Super. 231,

511 A.2d 709, 716 (N.J.Super.Ct.App.Div.1986) (citing *Callano v. Oakwood Park Homes Corp.*, 219 A.2d 232, 234 (N.J.Super.Ct.App.Div.1966)). To establish “unjust enrichment, a plaintiff must show both that defendant received a benefit and that retention of that benefit without payment would be unjust.” *VRG Corp. v. GKN Realty Corp.*, 135 N.J. 539, 554, 641 A.2d 519 (1994).

Here, Plaintiff’s allegations fail to support the claim of unjust enrichment. Even accepting all allegations as true, there is nothing in the record to suggest that Defendant’s retention of Plaintiff’s money is unjust. Plaintiff received the benefit of the product that he paid for and Defendant received the benefit of payment for said product. As such, the doctrine of unjust enrichment is inapposite here. Accordingly, the Court dismisses Plaintiff’s claim of unjust enrichment.

E. Plaintiff’s Breach of Express Warranty and Implied Warranty of Merchantability Claims (Counts VIII & IX)

*4 Plaintiff raises claims of breach of express and implied warranties. Specifically, Plaintiff alleges that he entered into a contract with Defendant for the purchase of the product, and in the contract, Defendant made express promises as to the purity of the product. (Compl.17). Additionally, Plaintiff claims that the implied warranty of merchantability was breached because the product “was not fit for the ordinary purpose for which it was intended to be used.” (*Id.* at 19, 641 A.2d 519). Defendant disagrees and argues that the warranty claims must be dismissed because “Plaintiff alleges no specific lead level in his product, and no actual injury from using the [p]roduct.” (Br.21).

Under New Jersey law, an express warranty is “[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain.” N.J. STAT. ANN. § 12A:2-313(1)(a). “The plaintiff in a warranty action need not establish the existence of a defect; the failure of the goods to perform as warranted is sufficient.” *Spring Motors Distrib., Inc. v. Ford Motor Co.*, 98 N.J. 555, 586, 489 A.2d 660 (1985). Proof of causation is also required, but “mere failure of promised performance is enough without proof of any defect.” *Realmuto v. Straub Motors, Inc.*, 65 N.J. 336, 343, 322 A.2d 440 (1974). To recover damages for breach of express warranty, plaintiffs must establish that such damages were reasonably foreseeable at the time that the contract was entered into. *Spring Motors Distrib., Inc.*, 98 N.J. at 579–80, 489 A.2d 660

(describing that damages for misrepresenting products comes from “society's interest in the performance of promises”).

An implied warranty “simply means that the thing sold is reasonably fit for the general purpose for which it is manufactured and sold.” *Henningsen v. Bloomfield Motors, Inc.*, 32 N.J. 358, 370, 161 A.2d 69 (1960). To establish a breach of implied warranty, plaintiff must show “that the product was not reasonably fit for the ordinary purposes for which it was sold and such defect proximately caused injury to the ultimate consumer.” *Hollinger v. Shoppers Paradise of New Jersey, Inc.*, 134 N.J.Super. 328, 340 A.2d 687, 692 (N.J.Super. Ct. Law Div.1975).

Here, Plaintiff fails to make the necessary showing of damages required for both a breach of express warranty claim

and an implied warranty of merchantability claim. Plaintiff merely asserts that some of Defendant's product contained 1.7 micrograms of lead. As such, Plaintiff fails to establish what damages resulted from the product containing said lead. Consequently, Plaintiff's claims of breach of express and implied warranty are dismissed.

IV. CONCLUSION

For these reasons, the Court GRANTS Defendant's Motion to Dismiss without prejudice. An appropriate Order follows this Opinion.

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TAB 23

 KeyCite Yellow Flag - Negative Treatment
Opinion Clarified on Denial of Reconsideration by [Horowitz v. AT&T Inc.](#), D.N.J., January 2, 2019

2018 WL 1942525

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Roy HOROWITZ, Linda Larson,
Kempton Pollard, Katherine Seaman,
and [Kathleen Sweeney](#), Plaintiffs,

v.

AT&T INC., AT&T Corp., AT&T Services, Inc.,
and AT&T Mobility Services LLC, Defendants.

Civil Action No. 3:17-cv-4827-BRM-LHG

|

Signed 04/25/2018

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[Angelo Joseph Genova](#), Genova Burns LLC, Newark, NJ, [James Bucci](#), Genova Burns LLC, Camden, NJ, for Defendants.

OPINION

[BRIAN R. MARTINOTTI](#), United States District Judge

*1 Before this Court are: (1) AT&T, Inc.’s (“INC”) ¹ Motion to Dismiss against Roy Horowitz (“Horowitz”), Linda Larson (“Larson”), Kempton Pollard (“Pollard”), Katherine Seaman (“Seaman”), and Kathleen Sweeney (“Sweeney,” collectively “Plaintiffs”) for lack of jurisdiction (ECF No. 21); (2) AT&T Services, Inc. (“SERVICES”) and AT&T Mobility Services, LLC’s (“MOBILITY”) Motion to Dismiss Larson and Pollard’s claims for lack of jurisdiction (ECF No. 23); and (3) AT&T Corp. (“CORP”), SERVICES, and MOBILITY’S Motion to Dismiss for failure to state a claim (ECF No. 22). ² Plaintiffs oppose all motions. (ECF Nos. 41, 42, and 43.) Pursuant to [Federal Rule of Civil Procedure 78\(a\)](#), the Court heard oral argument on April 10, 2018. For the reasons set forth below, INC’s Motion to Dismiss for lack

of jurisdiction is **DENIED**; SERVICES and MOBILITY’S Motion to Dismiss Larson and Pollard’s claims for lack of jurisdiction is **GRANTED**; and CORP, SERVICE, and MOBILITY’S Motion to Dismiss for failure to state a claim is **GRANTED in part and DENIED in part**.

- 1 Although at Oral Argument the Court stated it would refer to AT&T Inc. as AT&T, it has decided to refer to it as INC because Plaintiffs Complaint does not distinguish among the AT&T Defendants and instead refers to all Defendants collectively as AT&T. As articulated below, Plaintiffs argue all entities are a single entity, joint employers, or alter egos of one another. As such, the Court will only distinguish between Defendants when applicable.
- 2 INC, CORP, SERVICES, and MOBILITY will collectively be referred to as Defendants.

I. BACKGROUND

A. Factual Background

For the purposes of the motions to dismiss, the Court accepts the factual allegations in the Complaint as true and draws all inferences in the light most favorable to Plaintiffs. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). The Court also considers any “document *integral to or explicitly relied upon* in the complaint.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). This matter involves violations of the Age Discrimination in Employment Act (“ADEA”) in which, it is alleged, Defendants engaged in a “company-wide plan” to replace the aging workforce in Defendants’ corporations with a younger one by the year 2020 (the “2020 Scheme”), with a three-step “surplus” then termination and fraudulent release scheme. (See Compl. (ECF No. 1).)

1. The Parties

Horowitz is a citizen of the state of New Jersey. (*Id.* ¶ 1.) He was hired by AT&T in December 1995, and was employed at the company for more than 20 years before his termination effective June 21, 2016, at the age of 56. (*Id.* ¶ 141.) At the time of his termination, he worked in the Bedminster, New Jersey office and received his W-2 from CORP. (*Id.* ¶¶ 143–44.) From approximately 2014 until the time of his termination, he served as the Professional —Client Services Project Manager and reported to Peter

Marcinkowski (“Marcinkowski”), AT&T’s Senior Program Project Manager. (*Id.* ¶ 142.)

*2 Larson is a citizen of the state of Arizona. (*Id.* ¶ 3.) She was hired by AT&T in 1973, and was employed at the company for approximately 34 years before her termination effective March 7, 2016, at the age of 61. (*Id.* ¶ 100.) At the time of her termination, she worked “for AT&T from her home in Lake Havasu City, Arizona” and received her W-2 from SERVICES. (*Id.* ¶¶ 102–03.) From 2013 until the time of her termination, Larson served as the Manager of Sales Planning and reported to Glen Greenwell. (*Id.* ¶ 101.)

Pollard is a citizen of the state of Florida. (*Id.* ¶ 5.) He was hired by AT&T in May 2006, and was employed at the company for more than 10 years before his termination effective June 21, 2016, at the age of 69. (*Id.* ¶ 178.) At the time of his termination, Pollard worked for AT&T from his home in Bradenton, Florida and was assigned to an AT&T office in Tampa, Florida. (*Id.* ¶ 181.) He received his W-2 from SERVICES. (*Id.* ¶ 182.) From 2008 until the time of his termination, Pollard served as the Professional—Client Serves project Manager and reported to Marcinkowski. (*Id.* ¶ 179.)

Seaman is a citizen of the state of New Jersey. (*Id.* ¶ 7.) She was hired by AT&T in August 1986, and was employed at the company for more than 30 years before her termination effective March 27, 2017, at the age of 49. (*Id.* ¶ 255.) At the time of her termination, Seaman worked for AT&T in the Bedminster, New Jersey office and received her W-2 from SERVICES. (*Id.* ¶ 258–59.) From September 2004 until the time of her termination, she worked as a Director in marketing. (*Id.* ¶ 256.) Specifically, from January 2015 until her termination, she held the position of Director—Marketing Management in AT&T’s Entertainment Group and initially reported to Annette Isom, then Roger Hyde, then Craig Shirk, and ultimately David Banks. (*Id.* ¶ 257.)

Sweeney is a citizen of New Jersey. (*Id.* ¶ 9.) She was hired by AT&T in November 1997, and was employed at the company for more than 18 years before her termination effective July 22, 2016, at the age of 51. (*Id.* ¶ 216.) At the time of her termination, Sweeney worked for AT&T in King of Prussia, Pennsylvania, but travelled for work to field offices in various states, including New Jersey, and occasionally worked from her home in New Jersey. (*Id.* ¶ 219.) She received her W-2 from MOBILITY. (*Id.* ¶ 220.) From 2007 until the time of her termination, Sweeney served as the Director of Sales

(from January 2014 through April 2015, she held the position of Director of Sales Operations), and reported to Tiffany Baehman until 2016 and then Judy Cavalieri. (*Id.* ¶ 217.)

“[INC] is a Delaware corporation that is the parent company of several wholly-owned and controlled subsidiary corporations, including [SERVICES], MOBILITY, and [CORP].” (*Id.* ¶ 11.) It has its headquarters in Texas. (*Id.* at 1 (see caption).) CORP is a New York corporation with its principal place of business in Bedminster, New Jersey. (*Id.* ¶ 14.) CORP is duly registered to transact business in New Jersey, with a registered agent located in New Jersey for service of process. (*Id.*) SERVICES is a Delaware corporation. (*Id.* ¶ 15.) It is registered to transact business in New Jersey, with a registered agent located in New Jersey for service of process. (*Id.*) “It maintains several places of business located throughout the state of New Jersey, maintains systematic and continuous activity such that it is at home in New Jersey, and employs many people in the state of New Jersey.” (*Id.*) MOBILITY is a Delaware limited liability corporation. (*Id.* ¶ 16.) It is duly registered to transact business in New Jersey, with a registered agent in New Jersey for service of process. (*Id.*) “It maintains several places of business located throughout the state of New Jersey, maintains systematic and continuous activity such that it is at home in New Jersey, and employs many people in the state of New Jersey.” (*Id.*)

*3 Plaintiffs contend Defendants share “common ownership, management, administrative services, personnel, policies and employment practices.” (*Id.* ¶ 17.) Defendants hold themselves out to the public and their employees as a “family of companies” known as AT&T. (*Id.* ¶ 18.)

2. 2020 Scheme

Plaintiffs allege AT&T engaged in an intentional “pattern and practice of age discrimination adversely affecting [] Plaintiffs and similarly situated Older Workers.” (*Id.* ¶ 39–40.) AT&T allegedly came up with a corporate-wide plan to replace its older workforce with a younger one by 2020. (*Id.* ¶ 44.)

AT&T’s 2020 Scheme has allegedly been in effect since at least early 2013 and continues to this day. (*Id.* ¶ 53.) The 2020 Scheme operates in a three-step “surplus,” then termination, and fraudulent release scheme. (*Id.* ¶ 54.) Through a standard form and AT&T Surplus Notification Letter, AT&T

notifies certain employees that the company has been “evaluating certain business units within the AT&T family of companies. After a thorough and careful review, we have determined that the position which you currently hold will be eliminated. This is due to a reduction in positions within your level and organization. As a result of this decision, you will be placed on surplus status, effective the day following the date that appears at the top of this letter, and you may receive severance benefits if you meet the eligibility criteria.”

(*Id.* ¶ 57.) Plaintiffs claim the decisions as to who will be placed on surplus status are subjective and based on age discriminatory bias. (*Id.* ¶ 58.)

Employees selected for surplus had the opportunity to apply for alternative positions in AT&T by the end of the surplus period. (*Id.* ¶ 67.) However, at the conclusion of the surplus period, if an employee placed on surplus did not find an alternative position, their employment was terminated. (*Id.*) Plaintiffs allege “[t]he application and selection for available position process is infected with age bias.” (*Id.* ¶ 68.) “During the ‘surplus’ period, many employees who were notified of ‘surplus’ status, including those under age 40, secured available positions.” (*Id.* ¶ 77.)

After termination, the employees had an opportunity to receive a severance payment under the INC Severance Pay Plan if he or she executed the “GR&W-AT&T-Non-CA-GG-Amended September 2014” (the “General Release and Waiver”), which was presented to employees on the same day as the AT&T Surplus Notification Letter, as part of a standard uniform package. (*Id.* ¶¶ 62, 80.) “The General Release and Waiver purports to release all claims against AT&T with respect to the recipient’s employment and termination of employment, and to waive the right to be in or participate in a class, collective, or representative action on claims arising prior to signing, including under the ADEA.” (*Id.* ¶ 63.) The General Release and Waiver form was also accompanied by a standard form “stamped on the bottom as ‘Amended September 2014’ and entitled ‘AGE DISCRIMINATION IN EMPLOYMENT ACT (ADEA) INFORMATION NOTICE UNDER THE OLDER WORKERS BENEFIT PROTECTION ACT’” (the “OWBPA Notice”). (*Id.* ¶ 64.)

Plaintiffs argue the General Release and Waiver is invalid and unenforceable as to rights and claims under the ADEA, contains misstatements of facts, is misleading, was not

knowingly and voluntarily signed, and failed to comply with the strict disclosure requirements of the OWBPA. (*Id.* ¶ 82.) The General Release and Waiver allegedly fails to comply with the OWBPA because, among other things, it does not contain information about the decisional unit involved, eligibility factors for participation in the INC Severance Pay Plan, time limits applicable to the INC Severance Pay Plan, the job titles and ages of the employees designated to participate in INC Severance Pay Plan, and job titles and ages of those who were not selected to participate in the INC Severance Pay Plan. (*Id.* ¶ 82(a).)

*4 All Plaintiffs allege they received an AT&T Surplus Notification Letter, General Release and Waiver, and OWMPA Notice prior to their termination. (*Id.* ¶¶ 109, 115, 116, 151, 153, 154, 189, 191, 192, 225, 227, 228, 265, 268, 269.) Moreover, all Plaintiffs applied for at least two open and available positions with AT&T for which they were qualified, but were not interviewed or selected for any position. (*Id.* ¶¶ 126, 127, 163, 201, 241, 280.) All Plaintiffs but Larson signed the General Release and Waiver. (*Id.* ¶¶ 131, 167, 205, 246, 284.)

B. Procedural Background

On June 29, 2017, Plaintiffs filed a Complaint against Defendants alleging: (1) a violation of the ADEA, based on disparate treatment; (2) a violation of the ADEA, based on disparate impact; and (3) a violation of the OWBPA. (See ECF No. 1.) On September 25, 2017, Defendants filed three motions: (1) INC filed a Motion to Dismiss for Lack of Jurisdiction; (2) SERVICES and MOBILITY filed a Motion to Dismiss for lack of jurisdiction as to Plaintiffs Larson and Pollard’s claims; and (3) CORP, SERVICES, and MOBILITY filed a Motion to Dismiss for failure to state a claim. (ECF Nos. 21–23.) Plaintiffs oppose all motions. (See ECF Nos. 41–43.)

II. LEGAL STANDARDS

A. Federal Rule of Civil Procedure 12(b)(2)

On a motion to dismiss for lack of personal jurisdiction under **Federal Rule of Civil Procedure 12(b)(2)**, the plaintiff bears the burden of establishing the court’s jurisdiction over the defendant. *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 97 (3d Cir. 2004). Although the plaintiff must ultimately prove personal jurisdiction by a preponderance of the evidence, such a showing is unnecessary at the early stages of litigation. *Mellon Bank (E.) PSFS, Nat. Ass’n v. Farino*, 960 F.2d 1217,

1223 (3d Cir. 1992). Instead, the plaintiff must “present[] a prima facie case for the exercise of personal jurisdiction by establishing with reasonable particularity sufficient contacts between the defendant and the forum state.” *Id.* at 1223 (citations omitted). Because a Rule 12(b)(2) motion “is inherently a matter which requires resolution of factual issues outside the pleadings,” the jurisdictional allegations may be supported with sworn affidavits or other documents. *Metcalfe v. Renaissance Marine, Inc.*, 566 F.3d 324, 330 (3d Cir. 2009). Once the plaintiff meets his or her burden, the burden shifts to the defendant to establish the presence of other considerations that would render the exercise of personal jurisdiction unreasonable. *Carteret Sav. Bank, FA v. Shushan*, 954 F.2d 141, 150 (3d Cir. 1992) (citation omitted).

B. Federal Rule of Civil Procedure 12(b)(6)

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is “required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff].” *Phillips*, 515 F.3d at 228. “[A] complaint attacked by a ... motion to dismiss does not need detailed factual allegations.” *Bell Atl. v. Twombly*, 550 U.S. 544, 555 (2007). However, the Plaintiff’s “obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is “not bound to accept as true a legal conclusion couched as a factual allegation.” *Papasan*, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555.

*5 “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). “A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged.” *Id.* This “plausibility standard” requires the complaint allege “more than a sheer possibility that a defendant has acted unlawfully,” but it “is not akin to a ‘probability requirement.’” *Id.* (quoting *Twombly*, 550 U.S. at 556). “Detailed factual allegations” are not required, but “more than an unadorned, the defendant-harmed-me accusation” must be pled; it must include “factual enhancements” and not just conclusory statements or a

recitation of the elements of a cause of action. *Id.* (citing *Twombly*, 550 U.S. at 555, 557).

“Determining whether a complaint states a plausible claim for relief[is] ... a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 679. “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]’—‘that the pleader is entitled to relief.’” *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

While as a general rule, a court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to 12(b)(6), the Third Circuit has held “a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant under Rule 56].” *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any “‘document integral to or explicitly relied upon in the complaint.’” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426.

III. DECISION

A. Personal Jurisdiction Generally

“[A] federal district court may assert personal jurisdiction over a nonresident of the state in which the court sits to the extent authorized by the law of that state.” *Marten v. Godwin*, 499 F.3d 290, 296 (3d Cir. 2007) (quoting *Provident Nat'l Bank v. Cal. Fed. Sav. & Loan Ass'n*, 819 F.2d 434, 437 (3d Cir. 1987)). In New Jersey, “courts may exercise jurisdiction over a nonresident defendant to the uttermost limits permitted by the United States Constitution.” *Nicastro v. McIntyre Mach. Am., Ltd.*, 987 A.2d 575, 589 (2010), *rev'd on other grounds sub nom., J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873 (2011). “Accordingly, in determining whether personal jurisdiction exists, we ask whether, under the Due Process Clause, the defendant has certain minimum contacts with [New Jersey] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.” *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 316 (3d Cir. 2007).

Personal jurisdiction may be established through general jurisdiction or specific jurisdiction over a defendant. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011) (noting that “opinions in the wake of the pathmarking *International Shoe* decision have differentiated

between general or all-purpose jurisdiction, and specific or case-linked jurisdiction"). "For an individual, the paradigm for the exercise of general jurisdiction is the individual's domicile[.]" *Daimler AG v. Bauman*, 134 S. Ct. 746, 760 (2014). With respect to a corporation, in *Daimler*, the Supreme Court emphasized that the general jurisdiction inquiry "is not whether a foreign corporation's in-forum contacts can be said to be in some sense 'continuous and systematic,' [but] whether that corporation's 'affiliations with the State are so 'continuous and systematic' as to render [it] essentially at home in the forum State.'" *Id.* at 761 (quoting *Goodyear*, 564 U.S. at 919). The Supreme Court explained that "only a limited set of affiliations with a forum will render a defendant amenable to all-purpose jurisdiction there." *Id.* at 760. For a corporate defendant, "the place of incorporation and principal place of business are paradigm[...] bases for general jurisdiction." *Id.* (internal citation omitted).

*6 *Daimler* also recognized the possibility that, in an "exceptional" case, "a corporation's operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation at home in that State." *Id.* at 761 n.19. However, an approach that "approve[s] the exercise of general jurisdiction in every State in which a corporation engages in a substantial, continuous, and systematic course of business ... is unacceptably grasping." *Id.* at 761 (internal citation omitted). If general jurisdiction is established, a defendant can be sued in that jurisdiction on any matter. *Boswell v. Cable Servs. Co., Inc.*, No. 16-4498, 2017 WL 2815077, at *3 (D.N.J. June 29, 2017).

Specific jurisdiction may be established over a defendant where the defendant "has purposefully directed his activities at residents of the forum and the litigation results from alleged injuries that arise out of or relate to those activities." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (internal citations omitted). More specifically, specific jurisdiction requires that: "(1) the defendant purposefully directed its activities at residents of the forum, (2) the claim arises out of or relates to those activities, and (3) the assertion of personal jurisdiction is reasonable and fair." *WAG Acquistion, LLC v. Multi-Media, LLC*, No. 14-1661, 2015 WL 5310203, at *12 (D.N.J. Sept. 10, 2015) (citation omitted); *Shuker v. Smith & Nephew, PLC*, No. 16-3785, 2018 WL 1096185, at *14 (3d Cir. Mar. 1, 2018) (stating "what is necessary [for specific jurisdiction] is a deliberate targeting of the forum") (citation omitted).

A court's exercise of personal jurisdiction "requires some act by which the defendant purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws." *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 880 (2011) (emphasis added). Additionally, due process requires that "maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 (1984) (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)); *see also O'Connor*, 496 F.3d at 316 (discussing the three-step process in determining personal jurisdiction). Importantly, "the defendant's conduct and connection with the forum State [must be] such that he should reasonably anticipate being hauled into court there." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980). "[A] plaintiff's residence, by itself, is insufficient to establish personal jurisdiction" over a defendant. *Choi v. Damul Corp.*, No. 12-2440, 2014 WL 314669, at *7 (D.N.J. Jan. 27, 2014). "Once specific jurisdiction is established, a defendant can be sued in the jurisdiction only in the matter from which the jurisdiction arises." *Boswell*, 2017 WL 2815077, at *3.

1. INC

INC argues the Court lacks personal jurisdiction over it because it is solely a holding company with no contacts in New Jersey. (ECF No. 21-1 at 3.) Specifically, it argues there is no general jurisdiction because its place of incorporation is Delaware, its principal place of business is located in Texas, and Plaintiffs do not allege exceptional circumstances to support the exercise of general jurisdiction over it. (*Id.* at 6.) In addition, INC argues its subsidiaries, CORP, SERVICES, and MOBILITY are not its alter ego. (*Id.* at 11-15.) Lastly, INC argues there is no basis for specific jurisdiction over it because it has no minimum contacts with New Jersey, has no employees or real estate in New Jersey, does not insure persons or property in New Jersey, is not registered to do business in New Jersey, and neither produces goods or services nor advertises in New Jersey. (*Id.* at 8.)

*7 Plaintiffs contend this Court has general jurisdiction over INC because INC has vast contacts in New Jersey and is a single-employer or joint employer with CORP, SERVICES, and MOBILITY, and its subsidiaries are its alter ego. (See ECF No. 42.) In the alternative, Plaintiffs argue this Court has specific jurisdiction over INC because it committed and/or directed the 2020 Scheme. (*Id.* at 8-22.)

The Court finds there is no basis for exercising general jurisdiction over INC. Indeed, Plaintiffs admit INC is a Delaware corporation with its principal place of business in Texas. (ECF No. 1 ¶ 11 and at 1 (the caption of the Complaint).) *Daimler*, 134 S. Ct. at 760 (stating “the place of incorporation and principal place of business are paradigm[ic] ... bases for general jurisdiction”). Moreover, Plaintiffs do not otherwise allege any exceptional circumstances to support the exercise of general jurisdiction. *Id.* at 761 n.19 (recognizing the possibility that, in an “exceptional” case, “a corporation’s operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation at home in that State”). Plaintiffs do not allege that INC directly employed any individuals or directly maintained any business locations in New Jersey. Instead, it argues its subsidiaries hold principal places of business in New Jersey and employ people in New Jersey. (*Id.* ¶ 13.) Although Plaintiffs assert INC maintains systematic and continuous activity such that it is at home in New Jersey, this allegation is merely conclusory and unsupported by any factual allegations in the Complaint or affidavits.

The Court also finds there is no general jurisdiction based on a theory of “single employer,” “joint employer,” or alter ego of INC’s subsidiaries CORP, SERVICES, and MOBILITY. First, “single employer” or “joint employer” theories “and similar concepts are relevant for determining liability, but are not for determining whether a court may exercise personal jurisdiction over a party.” *In re Enter. Rent-A-Car Wage & Hour Emp’t Practices Litig.*, 735 F. Supp. 2d 277, 328 (W.D. Pa. 2010), *aff’d*, 683 F.3d 462 (3d Cir. 2012) (“The court is persuaded by the latter group of decisions in which the courts recognized that the joint employer theory and similar concepts are relevant for determining liability, but are not for determining whether a court may exercise personal jurisdiction over a party.”); *see Moreau v. Air France*, 356 F.3d 942, 944 (9th Cir. 2004) (stating joint employment does not determine personal jurisdiction); *Campanelli v. Image First Unif. Rental Serv., Inc.*, No. 15-04456, 2016 WL 4729173, at *7 (N.D. Cal. Sept. 12, 2016) (“[B]asing personal jurisdiction on joint employer status ... appears to be the minority view..... Even if [defendant] were liable under a ‘joint employer’ theory, this does not establish that a separate, non-resident corporate entity without minimum contacts can be haled into a California court.”); *E.E.O.C. v. Bass Pro Outdoor World, LLC*, 884 F. Supp. 2d 499, 525–26 (S.D. Tex. 2012) (“The integrated enterprise theory ... is a

liability standard ... not a jurisdictional standard.”); *Heidbrink v. ThinkDirect Mktg. Grp., Inc.*, No. 14-1232, 2014 WL 3585698 at *4 (M.D. Fla. 2014) (“A joint employer theory is relevant to establish liability against a defendant under the FLSA; it is not relevant to establish specific jurisdiction.”); *Vogt v. Greenmarine Holding, LLC*, No. 1-0311, 2002 WL 534542, at *3 (N.D. Ga. Feb. 20, 2002) (“Plaintiffs argue that the proper test for personal jurisdiction is whether OMC and Defendants constitute a ‘single employer’ so as to be liable under [a statute]. The court finds, however, that it is improper to conflate an issue of subject matter jurisdiction with personal jurisdiction. Liability and jurisdiction are two separate inquiries.”).

*8 Second, Plaintiffs allege this Court has general jurisdiction over INC based on the fact that CORP, SERVICES, and MOBILITY, which are subsidiaries of INC, are subject to the general jurisdiction of this Court and are alter egos of INC Courts in this District have applied the alter ego theory to cases of general jurisdiction. *See Mark IV Transp. & Logistics v. Lightning Logistics, Inc.*, 705 Fed.Appx. 103, 107 (3d Cir. 2017); *Bootay v. KBR, Inc.*, 437 Fed.Appx. 140, 143 (3d Cir. 2011); *Seltzer v. I.C. Optics, Ltd.*, 339 F. Supp. 2d 601, 609 (D.N.J. 2004). As such, the Court will apply the alter ego test in this matter.

“Whether the exercise of jurisdiction over a parent corporation is proper under the alter-ego theory depends upon the details of the unique relationship between the parent corporation and its subsidiary. The parent-subsidiary relationship itself is not sufficient to establish *in personam* jurisdiction over the parent entity.” *In re Enter. Rent-A-Car Wage & Hour Emp’t Practices Litig.*, 735 F. Supp. 2d at 317–18 (citation omitted); *see also Lucas v. Gulf & W. Indus., Inc.*, 666 F.2d 800, 805–06 (3d Cir. 1981) (remarking on factors relevant for jurisdictional analysis between a parent and a subsidiary), *abrogated on other grounds*, *EF Operating Corp. v. Am. Bldgs.*, 993 F.2d 1046 (3d Cir. 1993); *Carfagno v. Ace, Ltd.*, No. 04-6184, 2005 WL 1523530, at *6 (D.N.J. June 28, 2005) (same). In New Jersey, a subsidiary will be deemed to be the alter ego or “mere instrumentality” of its parent if “the parent so dominated the subsidiary that it had no separate existence but was merely a conduit for the parent.” *State, Dep’t of Envtl. Prot. v. Ventron Corp.*, 468 A.2d 150, 164 (N.J. 1983) (citations omitted). “It is patently clear since *Ventron* that in New Jersey even the exercise of significant control by the parent over the subsidiary will not suffice to pierce the corporate veil.” *Craig v. Lake Asbestos of Quebec, Ltd.*, 843 F.2d 145, 150 (3d Cir. 1988).

Courts consider factors such as: “(1) the level of capitalization of the subsidiary; (2) who the subsidiary does business with other than the parent; (3) the day-to-day involvement of the parent’s directors, officers and personnel with the subsidiary; and (4) the payment of the subsidiary’s salaries and expenses by the parent.” *Seltzer*, 339 F. Supp. 2d at 610; *Dewey v. Volkswagen AG*, 558 F. Supp. 2d 505, 513 (D.N.J. 2008) (citations omitted) (listing the factors to consider as: “(1) whether the subsidiary is doing business in the forum that would otherwise be performed by the parent; (2) whether there is common ownership of the parent and a subsidiary; (3) whether there is financial dependency; and (4) whether the parent interferes with the subsidiary’s personnel, disregards the corporate formalities, and/or controls the subsidiary’s marketing and operational policies.”). Liability generally requires that the parent corporation “abused the privilege of incorporation by using the subsidiary to perpetuate a fraud or injustice, or otherwise to circumvent the law.” *Patent Incentives, Inc. v. Seiko Epson Corp.*, No. 88-1407, 1988 WL 92460, at *6 (D.N.J. Sept. 6, 1988), *aff’d*, 878 F.2d 1446 (Fed. Cir. 1989) (citing *Ventron*, 468 A.2d at 164).

A parent company’s domination or control of its subsidiary cannot be established by overlapping boards of directors. *See United States v. Bestfoods*, 524 U.S. 51, 69 (1998) (“It is a well-established principle [of corporate law] that directors and officers holding positions with a parent and its subsidiary can and do ‘change hats’ to represent the two corporations separately, despite their common ownership.”); *Leo v. Kerr-McGee*, No. 93-1107, 1996 WL 254054, at *6 (D.N.J. May 10, 1996) (“A significant degree of overlap between directors and officers of a parent and its subsidiary does not establish an alter ego relationship.”). There is a general presumption “that the directors are wearing their ‘subsidiary hats’ and not their ‘parent hats’ when acting for the subsidiary,” so dual office holding alone is not sufficient to establish liability. *Bestfoods*, 524 U.S. at 69 (citation omitted).

*9 The record does not support a finding that INC dominates over its subsidiaries in such a manner that the subsidiaries are mere conduits of INC. INC is purely a holding company, that conducts no business with the public; has no employees in New Jersey; no office or mailing address in New Jersey; does not own, lease, manage, or maintain any real property in New Jersey; is not an insurance company; does not pay income, property or franchise taxes to the state of New Jersey; does not engage in any advertising in New Jersey; and does not provide or place in the stream of commerce

in New Jersey any product. (See ECF No. 21-2.) As other courts have stated, a “holding company could simply hold another type of subsidiary.” *In re Enter. Rent-A-Car Wage & Hour Emp’t Practices Litig.*, 735 F. Supp. 2d at 324 (quoting *Action Mfg. Co., Inc. v. Simon Wrecking Co.*, 375 F. Supp. 2d 411, 422 (E.D. Pa. 2011)). Indeed, at least one other court in this circuit, when analyzing multiple factors in a similar situation involving a holding company, has concluded that in “an ordinary holding company/subsidiary relationship, not one of undue domination and control,” there is no alter ego relationship. *Arch v. Am. Tobacco Co.*, 984 F. Supp. 830, 837-38 (E.D. Pa. 1997). Plaintiffs have failed to plead: (1) financial dependency of either subsidiary on INC; (2) undercapitalization of any of INC’s subsidiaries; (3) INC paying the salaries and expenses of any INC subsidiary; (4) INC controlling the subsidiary’s marketing and operational policies; (5) facts demonstrating the entities share the same day-to-day operations; (6) share similar employees; or (7) evidence of INC’s every day involvement and control over any of its subsidiaries.

Instead, Plaintiffs rely on the fact that INC and its subsidiaries share the AT&T website, which has no separate pages or links devoted to any particular subsidiary; that INC and its subsidiaries all use @att.com email addresses; that INC and its subsidiaries share employment policies and codes of ethics; and that INC and its subsidiaries portray themselves as a single brand and to the public as the “AT&T family of companies.” (ECF No. 42 at 9.) However, courts have found that “common marketing image and joint use of trademark logs fail to render [entities as] alter ego[s].” *In re Enter. Rent-A-Car Wage & Hour Emp’t Practices Litig.*, 735 F. Supp. 2d at 323; *see Prescott v. LivaNova PLC*, No. 16-00472, 2017 U.S. Dist. LEXIS 95830, at *25-26, 2017 WL 2591270 (S.D. Iowa June 12, 2017) (granting a motion to dismiss where “[t]he companies share a common branding scheme, including a common email domain, but maintain completely separate day-to-day operations, employees, officers, and corporate structures”); *Gloria D. Wiseman v. ING Grp., N.V. et al.*, No. 16-07587, 2017 WL 4712417, at *13 (S.D.N.Y. Sept. 28, 2017) (finding that “the fact that ReliaStar personnel used voya.com email addresses or mention ReliaStar’s relationship to Voya is no more than a different form of the argument that the two identified under the same brand, which courts have found insufficient as a matter of law to establish alter egos”); *Patterson v. Home Depot, USA, Inc.*, 684 F. Supp. 2d 1170, 1179 (D. Ariz. 2010) (holding that “[t]he fact the two companies used the same logo and intellectual property pursuant to the licensing agreement [] does not

demonstrate that Krause-Werk was the alter ego of the other"); *Von Grabe v. Sprint PCS*, 312 F. Supp. 2d 1285, 1301 (S.D. Cal. 2003) (holding that common trade name and logo, without more, is not a sufficient basis for establishing personal jurisdiction) (internal citations omitted). Moreover, a company being "portrayed as a single brand to the public ... does not demonstrate the necessary control by defendant parent over the subsidiaries." *In re Enter. Rent-A-Car Wage & Hour Emp't Practices Litig.*, 735 F. Supp. 2d at 323.

Accepting Plaintiffs' position would extend the alter ego doctrine, such that entities utilizing the same brand, website, and policies would be imputed as alter egos, without demonstrating the subsidiaries ignored corporate formalities in day-to-day activities, the subsidiaries financially relied on INC, INC's subsidiaries were undercapitalized, INC paid the salaries and expenses of any INC subsidiary, and the entities shared similar employees. Accordingly, the Court finds CORP, SERVICES, and MOBILITY are not alter egos of INC. As such, the Court lacks general jurisdiction over INC.

Third, Plaintiffs argue this Court has specific jurisdiction over INC because it initiated, directed, and benefited from the 2020 Scheme. (ECF No. 42 at 14–26.) The Court finds Plaintiffs have plead sufficient facts and submitted adequate evidence to establish specific jurisdiction as to INC at this stage of the litigation. "In ruling upon a motion to dismiss, courts must accept the plaintiff's allegations as true and construe disputed facts in favor of the plaintiff." *Machulsky v. Hall*, 210 F. Supp. 2d 531, 537 (D.N.J. 2002) (citing *Carteret Sav. Bank, F.A.*, 954 F.2d at 142 n.1).

*10 As stated above, specific jurisdiction requires t: "(1) the defendant purposefully directed its activities at residents of the forum, (2) the claim arises out of or relates to those activities, and (3) the assertion of personal jurisdiction is reasonable and fair." *WAG Acquisition, LLC*, 2015 WL 5310203, at *12 (citation omitted). The General Release and Waiver directed at Plaintiffs, some of which are New Jersey residents (Larson, Sweeney, Seaman), offered an "[]INC Severance Pay Plan" if the terminated employees signed the release. (ECF No. 16–6 at 8.) After termination, the employees had an opportunity to receive a severance payment under the INC Severance Pay Plan if he or she executed the General Release and Waiver, which was presented to employees on the same day as the AT&T Surplus Notification Letter, as part of a standard uniform package. (ECF No. 1 ¶¶ 62, 80.) In fact, the INC Severance Pay Plan is listed

in INC's Form 5500, Annual Return/Report of Employee Benefit Plan. (ECF No. 42–12 at 21–26.) As such, Plaintiffs have established INC purposefully directed activities (the 2020 Scheme) at New Jersey residents and the claims in this matter clearly arise out of the 2020 Scheme, which included the INC Severance Pay Plan. Moreover, personal jurisdiction is reasonable and fair because INC should have anticipate being hauled into court due to its Severance Pay Plan. *World-Wide Volkswagen Corp.*, 444 U.S. at 297.

INC argues that it does not have any of the minimum contacts with New Jersey necessary for specific jurisdiction because

[INC] is a Delaware corporation with its principal place of business in Dallas, Texas. It is and has always been a holding company. It has no employees or real estate in New Jersey. It does not insure persons or property in New Jersey. It does not pay taxes in New Jersey. [INC] is not registered to do business in New Jersey and it neither produces goods or services nor advertises in New Jersey. Simply put, [INC] has no presence, operations, or contracts in this form.

(ECF No. 21–1 at 8.) However, this argument ignores the fact that INC purposefully directed its 2020 Scheme, Severance Pay Plan at residents of New Jersey and the claims in this matter arises out of those activities. As such, the Court finds at this time Plaintiffs have demonstrated specific jurisdiction over INC. Accordingly, INC's Motion to Dismiss based on lack of personal jurisdiction is **DENIED**.

Lastly, INC argues Plaintiffs did not properly serve INC with the Complaint. (ECF No. 21–1 at 15–16.) Plaintiffs argue they properly served INC, and that assuming service was improper they timely addressed any defect. (ECF No. 42 at 29–30.) Because the ADEA "does not provide a means for service of process, a federal court may exercise personal jurisdiction over a nonresident of the state in which the court sits to the extent authorized by the law of that state." *Bane v. Netlink, Inc.*, 925 F.2d 637, 639 (3d Cir. 1991); *Swaim v. Moltan Co.*, 73 F.3d 711, 719 (7th Cir. 1996) ("The [ADEA] does not provide for nationwide service of process, and one must therefore resort to [state] law for service of process.").

Under New Jersey law, personal service is the primary method of effecting service. *See N.J. Ct. R. 4:4-4(a), 4:4-5(a).* New Jersey Court Rules 4:4-3 and 4:4-4(a) prescribe the methods of effecting personal service within the state. Substitute or constructive service, however, is permitted when personal service within the state cannot be effected. *See N.J. Ct. R. 4:4-4(b), 4:4-5.* For *in personam* jurisdiction, New Jersey Court Rule 4:4-4(b) provides the methods of substitute or constructive service, such as personal service outside the state, simultaneous mailings by ordinary and certified (or registered) mail, and “as provided by court order, consistent with due process of law.” *N.J. Ct. R. 4:4-4(b)(1), (b)(3).* For *in rem* and *quasi in rem* jurisdiction, New Jersey Court Rule 4:4-5 provides the methods for personal, substitute, and constructive service, such as service by publication. Regardless of the type of action, substitute or constructive service requires a demonstration of due diligence that satisfies the requirements specified in New Jersey Court Rule 4:4-5(b). *See N.J. Ct. R. 4:4-5(a); 4:4-4(b)(1)* (cross-referencing Rule 4:4-5(b)); N.J. Ct. R. 4:4(b)(3) (noting that service by a court order consistent with due process is precluded “[i]f service can be made by any of the modes provided by this rule”). As such, service of process outside the State requires an “affidavit satisfying the requirements of R. 4:4-5(b) that despite diligent effort and inquiry personal service cannot be made in accordance with paragraph (a) of this rule.” *N.J. Ct. R. 4:4-4(b).*

*11 On July 25, 2017, Plaintiffs served a Summons and Complaint on INC in Delaware. (ECF No. 4 and 11) Initially, Plaintiffs failed to attach an affidavit as required pursuant to New Jersey Court Rule 4:4-4(b). However, such defect has been timely addressed and cured on September 27, 2017. (Aff. of Inquiry (ECF No. 27)); *see Fed. R. Civ. P. 4(m)* (stating a defendant must be served within 90 days after the complaint is filed). As such, INC’s Motion to Dismiss on this basis is DENIED.

2. Larson and Pollard’s Claims Against SERVICES and MOBILITY

SERVICES and MOBILITY argue Larson and Pollard’s claims against them should be dismissed for lack of personal jurisdiction. (*See* ECF No. 23.) Plaintiffs contend this Court has jurisdiction over Larson and Pollard’s claims against SERVICES and MOBILITY because: (1) SERVICES and MOBILITY consented to general jurisdiction in New Jersey;

(2) SERVICES and MOBILITY purposefully directed their 2020 Scheme at New Jersey; and (3) SERVICES and MOBILITY are part of the “AT&T family of companies,” such that they are alter egos of INC and all AT&T entities are a single employer, and the “AT&T family of companies” purposefully directed their 2020 Scheme at New Jersey. (*See* ECF No. 43.) The Court will address these arguments in turn.

Plaintiffs claim the Court has general jurisdiction over SERVICES and MOBILITY by virtue of them having registered to do business in New Jersey and having registered agents in the state of New Jersey. (ECF No. 43 at 5-8.) This District is split on the issue of whether the mere fact that a corporation is registered to do business in New Jersey and appointed an agent to receive process subjects it to general jurisdiction in New Jersey.

In *Otsuka Pharm. Co. v. Mylan Inc.*, Chief Judge Jerome B. Simandle addressed the issue of whether a corporation’s registration to do business and appointment of a registered agent for service of process in New Jersey subjects the corporation to personal jurisdiction in New Jersey. 106 F. Supp. 3d 456, 467 (D.N.J. 2015). In relying on two Supreme Court cases from the first half of the twentieth century, prior to *Daimler*, Chief Judge Simandle concluded “a corporation’s appointment of an agent for service of process constitutes, under certain circumstances, consent to the forum’s personal jurisdiction.” *Id.* (citing *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165 (1939); *Pa. Fire Ins. Co. of Phila. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93, 95 (1917)). He reasoned that “in appointing an agent, a foreign corporation ‘takes the risk of the construction that will be put upon the [registration] statute and the scope of the agency by the State Court.’” *Id.* at 468 (quoting *Robert Mitchell Furniture Co. v. Selden Breck Const. Co.*, 257 U.S. 213, 216 (1921)).

Chief Judge Simandle also relied on a decision from the Third Circuit, *Bane v. Netlink, Inc.*, where the Court found that “by registering to do business in Pennsylvania, the defendant purposefully availed itself of the privilege of conducting activities within the forum State, th[u]s invoking the benefits and protections of its laws.” *Otsuka Pharm.*, 106 F.3d at 468 (quoting *Bane v. Netlink, Inc.*, 925 F.2d 637, 640 (3d Cir. 1991)). Chief Judge Simandle concluded that the Supreme Court’s decision in *Daimler* did not preclude jurisdiction through a corporation’s consent by means of registration and appointment of an agent for service of process. *Id.* Chief Judge Simandle reasoned that *Daimler* concerned non-consensual general jurisdiction over a corporation but did not

“cast any doubt on the continued vitality of consent-based jurisdiction.” *Id.* Therefore, he found that two of the defendant corporations in that matter consented to jurisdiction in New Jersey by means of registering to do business and appointing a registered agent. *Id.* at 470; *see also Senju Pharm. Co. v. Metrics, Inc.*, 96 F. Supp. 3d 428, 438 (D.N.J. 2015) (another opinion by Chief Judge Simandle finding that “acceptance of service by a defendant registered to do business in the state establishes personal jurisdiction”); *Sadler v. Hallsmith SYSCO Food Servs.*, No. 08-4423, 2009 WL 1096309, at *2 (D.N.J. Apr. 21, 2009) (“Because the Court finds that [the defendant corporation] consented to being sued in the courts of New Jersey, the Court need not engage in an analysis of [the defendant corporation’s] contacts with the state.”).

*12 However, in another decision from this District, Judge Madeline Cox Arleo reached the opposite conclusion. In *Display Works, LLC v. Bartley*, she found that a corporation did not consent to jurisdiction in New Jersey merely by registering to do business there and appointing an agent for service of process. 182 F. Supp. 3d 166, 179 (D.N.J. 2016). Judge Arleo had two primary reasons to support her conclusion. First, she distinguished the Third Circuit’s decision in *Bane*. Judge Arleo notes, in *Bane*, the Third Circuit was interpreting Pennsylvania’s registration statute, which provided that by registering to do business in Pennsylvania and designating an agent for service of process, a corporation consents to personal jurisdiction there. *Id.* at 173–75. Unlike the Pennsylvania registration statute, the New Jersey statute does not expressly state that a corporation consents to jurisdiction when it registers to do business in New Jersey and appoints an agent for service of process. *Id.* at 174–75. Therefore, Judge Arleo concluded that “*Bane* compels the Court to find that the New Jersey statutory scheme does not permit [general] jurisdiction by consent by virtue of registration to do business here or actually doing business here.” *Id.* at 175.

Second, Judge Arleo found that the early Supreme Court decisions relied upon by the court in *Otsuka Pharmaceutical* “developed from an outmoded way of thinking about jurisdiction” and were inconsistent with the Supreme Court’s recent decision in *Daimler*. *Id.* at 176–77. Judge Arleo reasoned that

[t]he sweeping interpretation that a state court gave to a routine registration statute and an

accompanying power of attorney that *Pennsylvania Fire* credited as a general consent has yielded to the doctrinal refinement reflected in *Goodyear* and *Daimler* and the Court’s 21st century approach to general and specific jurisdiction in light of expectations created by the continuing expansion of interstate and global business.

Id. at 178 (quoting *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 639 (2d Cir. 2016)). Therefore, Judge Arleo concluded that a corporation’s registration to do business in New Jersey and appointment of an agent for service of process in New Jersey does not subject the corporation to general personal jurisdiction in New Jersey. *Id.* at 179; *see Boswell*, 2017 WL 2815077, at *6 (concluding the defendant’s registration to do business in New Jersey did “not mean it consented to general jurisdiction in New Jersey”); *Kubin v. Orange Lake Country Club, Inc.*, No. 10-1643, 2010 WL 3981908, at *3 (D.N.J. Oct. 8, 2010) (“Filing a certificate to do business in New Jersey [is] insufficient to establish general jurisdiction, absent evidence that [defendant] was actually doing business in New Jersey.”); *Smith v. S & S Dundalk Eng’g Works, Ltd.*, 139 F. Supp. 2d 610, 620 (D.N.J. 2001) (same); *Atkinson & Mullen Travel, Inc. v. New York Apple Tours Inc.*, 48 U.S.P.Q.2d 1377, 1379 (D.N.J. 1998) (having a license to conduct business in New Jersey is not “in and of itself sufficient to establish continuous and substantial contacts”); *Wenche Siemer v. Learjet Acquisition Corp.*, 966 F.2d 179, 183 (5th Cir. 1992) (qualification to do business in a state is “of no special weight” in evaluating general jurisdiction), *cert. denied*, 506 U.S. 1080 (1993); *Dutch Run–Mays Draft, LLC v. Wolf Block, LLP*, 164 A.3d 435, 444 (N.J. Super. Ct. App. Div. 2017) (“We cannot agree business registration rises to consent to submit to the general jurisdiction in the forum.”).

The Court finds Judge Arleo’s reasoning in *Display Works* persuasive. The Court agrees that *Bane* is distinguishable due to the differences in the Pennsylvania and New Jersey corporation registration statutes. Notably, the New Jersey Statute does not contain any express language to put a corporation on notice that by registering to do business in New Jersey, it is also consenting to personal jurisdiction in the state. *See N.J.S.A. 14A:1-1 et seq.; World–Wide Volkswagen*, 444 U.S. at 291 (“Due process requires that the defendant be given adequate notice of the suit and be subject to the

personal jurisdiction of the court.” (internal citation omitted)). Furthermore, the Court finds that consent by registration is inconsistent with *Daimler*. *Daimler* reiterated the principal from *Goodyear* that there is general jurisdiction over a corporation in its place of incorporation and its principal place of business. *Daimler*, 134 S. Ct. at 760. *Daimler* also advised that older decisions addressing general jurisdiction over a corporation should be afforded little weight. *Id.* at 761 n.18 (stating that cases “decided in the era dominated by *Pennoyer*’s territorial thinking should not attract heavy reliance today” (citation omitted)). Accordingly, the Court finds SERVICES and MOBILITY did not consent to personal jurisdiction by mere registration and appointment of an agent for service of process in the state of New Jersey.

*13 Because registration and appointment of an agent for service of process in the state of New Jersey does not provide for general jurisdiction, the question remains whether there is another basis for general jurisdiction as to SERVICES and MOBILITY. As previously stated, for a corporate defendant, “the place of incorporation and principal place of business are paradigm[es] bases for general jurisdiction.” *Daimler*, 134 S. Ct. at 760 (internal citation omitted). *Daimler* also recognized the possibility that, in an “exceptional” case, “a corporation’s operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation at home in that State.” *Id.* at 761 n.19. However, an approach that “approve[s] the exercise of general jurisdiction in every State in which a corporation engages in a substantial, continuous, and systematic course of business ... is unacceptably grasping.” *Id.* at 761 (internal citation omitted).

Plaintiffs admit SERVICES and MOBILITY are Delaware corporations. (*Id.* ¶ 16.) Moreover, Plaintiffs acknowledge in the caption of the Complaint that SERVICES is headquartered in Texas and MOBILITY is headquartered in Georgia. (See ECF No. 1.) Plaintiffs do not allege in the Complaint that New Jersey is the principal place of business of SERVICES or MOBILITY. Instead, they contend SERVICES and MOBILITY maintain “several places of business located throughout the state of New Jersey, maintains systematic and continuous activity such that it is at home in New Jersey, and employs many people in the state of New Jersey.” (*Id.* ¶¶ 15–16.) However, this is not sufficient. Only in an “exceptional” case can “a corporation’s operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render

the corporation at home in that State.” *Daimler*, 134 S. Ct. at 761 n.19. In *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, 137 S. Ct. 1773, 1777–78 (2017), the Supreme Court found the California court lacked personal jurisdiction over a pharmaceutical company that engaged in business in California, maintained five research and laboratories in California, and employed hundreds of employees in California, and maintained a small state-government advocacy office in California. Accordingly, the Court finds SERVICES and MOBILITY are not subject to general jurisdiction in New Jersey.

The Court also finds SERVICES and MOBILITY are not subject to jurisdiction in New Jersey as to Larson and Pollard’s claims under the theories of single employer or alter ego. First, “single employer” or “joint employer” theories “and similar concepts are relevant for determining liability, but are not for determining whether a court may exercise personal jurisdiction over a party.” *In re Enter. Rent-A-Car Wage & Hour Emp’t Practices Litig.*, 735 F. Supp. 2d at 328. Furthermore, as determined above, INC is not the alter ego of its subsidiaries. Thus, the fact that the Court found it has jurisdiction over INC is irrelevant and does not implicate jurisdiction over SERVICES or MOBILITY.

Moreover, to the extent Plaintiffs argue SERVICES and MOBILITY are alter egos of CORP or vice versa and therefore subject to personal jurisdiction, SERVICES and MOBILITY are not alter egos of CORP, a New York corporation with its principal place of business in Bedminster, New Jersey. (ECF No. 1 ¶ 14.) The record does not support a finding that SERVICES or MOBILITY dominate over CORP or vice versa, in such a manner that CORP is a mere conduit of SERVICES or MOBILITY. There is no evidence in the record of CORP’s: (1) financial dependency of either SERVICES or MOBILITY; (2) undercapitalization of CORP; (3) SERVICES or MOBILITY paying the salaries and expenses of CORP; (4) SERVICES or MOBILITY controlling CORP’S marketing and operational policies; (5) evidence demonstrating the entities share the same day-to-day operations; (6) share similar employees; or (7) evidence of SERVICES or MOBILITY every day involvement and control over CORP. The fact CORP, SERVICES, and MOBILITY, use the same brand “AT & T”; the AT&T website has no separate pages or links devoted to any particular subsidiary; all entities use @att.com email addresses; CORP, SERVICES, and MOBILITY share employment policies and codes of ethics; and that CORP, SERVICES, and MOBILITY portray themselves as a single brand and to the public as the

“AT&T family of companies,” is not enough. (ECF No. 43 at 11–18, 23–24.) Courts have found that common marketing image, common branding, common email domain, and joint use of trademark logs, fail to render entities as alter egos if they maintain completely separate day-to-day activities. *See In re Enter. Rent-A-Car Wage & Hour Emp’t Practices Litig.*, 735 F. Supp. 2d at 323; *see Prescott*, 2017 U.S. Dist. LEXIS 95830, at *25–26, 2017 WL 2591270; *Gloria D. Wiseman*, 2017 WL 4712417, at *13; *Patterson*, 684 F. Supp. 2d at 1179; *Von Grabe*, 312 F. Supp. 2d at 1301. Thus, the fact the Court has jurisdiction over CORP is irrelevant and does not implicate jurisdiction over SERVICES or MOBILITY.

*14 Lastly, the Court finds SERVICES and MOBILITY are not subject to specific jurisdiction in New Jersey over Larson or Pollard’s claims. SERVICES and MOBILITY move to dismiss Larson and Pollard’s claims, arguing that *Bristol-Myers* bars their claims. (ECF No. 8–12.) Specifically, SERVICES and MOBILITY argue that even though they have contacts in New Jersey (business locations and employees in New Jersey), their contacts do not relate to Larson or Pollard and do not arise out of those contacts because neither Larson nor Pollard worked in New Jersey. (*Id.*) They further argue Larson and Pollard cannot “piggy-back” on the claims and jurisdiction of the other named plaintiffs where the Court has specific jurisdiction over their claims as to SERVICES and MOBILITY. (*Id.* at 10.)

Plaintiffs claim there is specific jurisdiction over SERVICES and MOBILITY because they have direct contacts with New Jersey and because they purposefully directed activities at New Jersey residents. (ECF No. 43 at 18–22.) Plaintiffs further argue that *Bristol-Myers* does not apply to bar Larson and Pollard’s claims because *Bristol-Myers* concerned a mass action asserting state claims in state court and is therefore inapposite to the federal class action claims asserted here. (ECF No. 43 at 25–26.)

Specific jurisdiction requires that: “(1) the defendant purposefully directed its activities at residents of the forum, (2) the claim arises out of or relates to those activities, and (3) the assertion of personal jurisdiction is reasonable and fair.” *WAG Acquistion, LLC*, 2015 WL 5310203, at *12 (citation omitted).

Bristol-Myers involved a Fourteenth Amendment due-process challenge to claims asserted by non-Californian plaintiffs in a mass civil action filed against Bristol-Myers in a California state court for injuries allegedly caused by

a drug called *Plavix*. *Bristol-Myers*, 137 S. Ct. at 1777–79, 1787, 1789. Bristol-Myers, a citizen of Delaware and New York, challenged the California Supreme Court’s application of a “sliding scale approach to specific jurisdiction,” under which it held that although general jurisdiction was lacking in California because Bristol-Myers did not: (1) develop *Plavix* in California, (2) create a marketing strategy for *Plavix* in California, (3) manufacture, label, or package *Plavix* in California, or (4) work on the regulatory approval of *Plavix* in California; and the nonresident plaintiffs did not allege that: (1) they obtained *Plavix* through California physicians or other California sources, (2) were injured by *Plavix* in California, or (3) were treated for their injuries in California, the California state court nevertheless had personal jurisdiction over Bristol-Myers as to the claims of the nonresident plaintiffs as well as the resident plaintiffs. *Id.* at 1778–79. The California court reasoned that because Bristol-Myers had “extensive contacts with California” it permitted the exercise of specific jurisdiction “based on a less direct connection between [Bristol-Myers’s] forum activities and plaintiffs’ claims than might otherwise be required.” *Id.* at 1778–79 (quoting *Bristol-Myers*, 377 P.3d at 887–89).

On appeal, the United States Supreme Court found the California rational amounted to a “loose and spurious form of general jurisdiction” and held that, because the California approach had allowed for claims to proceed against Bristol-Myers despite the lack of a connection between the forum and the specific claims at issue, the approach did not comport with “settled principles of personal jurisdiction” and exceeded due process limits. *Bristol-Myers*, 137 S. Ct. at 1781–83. However, the Supreme Court limited its decision; because “[its] decision concern[ed] the due process limits on the exercise of specific jurisdiction by a State, [it] le[ft] open the question whether the Fifth Amendment imposes the same restrictions on the exercise of personal jurisdiction by a federal court.” *Id.* at 1783–84 (citing *Omni Capital Int’l, Ltd. v. Rudolf Wolff & Co.*, 484 U.S. 97, 102 n.5 (1987)).

*15 Courts have found *Bristol-Myers* also resolved the question of whether, absent a connection between a state and the specific claims brought by a nonresident named class action plaintiff against a defendant not subject to general jurisdiction in that state, a court may nonetheless exercise specific jurisdiction over those claims because they are similar or identical to claims brought in the same case by a resident named plaintiff against the same defendant. First, while *Bristol-Myers* addressed state law claims, courts have found that nothing in *Bristol-Myers* suggests that it

does not apply to named plaintiffs in a federal putative class action. *See In re Dental Supplies Antitrust Litig.*, No. 16-696, 2017 WL 4217115, at *9 (E.D.N.Y. Sept. 20, 2017) (“The constitutional requirements of due process do[] not wax and wane when the complaint is individual or on behalf of a class. Personal jurisdiction in class actions must comport with due process just the same as any other case.”); *Greene v. Mizuho Bank, Ltd.*, No. 14-1437, 2017 WL 7410565, at *4 (N.D. Ill. Dec. 11, 2017) (“Nothing in *Bristol-Myers* suggests that it does not apply to named plaintiffs in a putative class action; rather, the Court announced a general principal—that due process requires a connection between the forum and the specific claims at issue. That principle applies with equal force whether or not the plaintiff is a putative class representative.”) (citations omitted).

These same courts have also found that a court does not have specific jurisdiction over individual claims asserted by nonresident named plaintiffs because there is no connection between their claims and the corporation’s activities within the forum, even if those claims are similar or identical to claims brought in the same case by a resident named plaintiff against the same defendant. *See Sanchez v. Launch Tech. Workforce Sols., LLC*, No. 17-01904, 2018 WL 942963, at *1 (N.D. Ga. Feb. 14, 2018) (finding “individual members of a plaintiff class, *aside from named representatives*, need not satisfy the “minimum contacts” test in order for a [] forum court to exercise personal jurisdiction over them”) (emphasis added) (citation omitted); *Greene*, 2017 WL 7410565, at *4 (“[D]ue process requires a connection between the forum and the specific claims at issue. That principle applies with equal force whether or not the plaintiff is a putative class representative.”) (citations omitted); *Wenokur v. AXA Equitable Life Ins. Co.*, No. 17-00165, 2017 WL 4357916, at *4 (D. Ariz. Oct. 2, 2017) (finding it “lacks personal jurisdiction over the claims of putative class members with no connection to Arizona and therefore would not be able to certify a nationwide class”); *Covington v. Janssen Pharm., Inc.*, No. 17-1588, 2017 WL 3433611, at *5 (E.D. Mo. Aug. 10, 2017) (finding that because “53 of the 54 total plaintiffs failed to allege that they ingested the drug in the state of Missouri or suffered from resulting injuries in Missouri. Instead, those 53 plaintiffs allege only that the defendants transacted business and committed torts in the State of Missouri. But those plaintiffs were not injured from the defendants’ contacts with the state of Missouri. Because the 53 plaintiffs’ claims do not arise out of the defendants’ contacts with the state of Missouri, this Court lacks specific personal jurisdiction over their claims”).

In an effort to distinguish *Bristol-Myers*, Plaintiffs rely on *Swamy v. Title Source, Inc.*, No. 17-01175, 2017 WL 5196780 (N.D. Cal. Nov. 10, 2017). However, *Swamy* is not inconsistent with *Bristol-Myers* or the cases cited above. In *Swamy*, a California resident brought a putative class action under the Fair Labor Standards Act (“FLSA”) on behalf of himself and others similarly situated, including nonresident employees of the defendant. *Id.* at *1-2. The defendant moved to dismiss the cases against the nonresident, putative opt-in plaintiffs for lack of personal jurisdiction. *Id.* at 1. The Court rejected the argument that *Bristol-Myers* precludes a court from exercising personal jurisdiction over the claims of *out-of-state opt-in plaintiffs in a collective action proceeding under the FLSA*. *Id.* at 2.

Here, in contrast to *Swamy*, Larson and Pollard are not nonresident, putative opt-in plaintiffs, instead they have affirmatively brought this putative class action as named plaintiffs. Therefore, there must be a connection between their claims and SERVICES and MOBILITY activities within New Jersey, even if Larson and Pollard’s claims are similar or identical to claims brought by the resident named plaintiffs. *See Sanchez*, No. 17-01904, 2018 WL 942963, at *1 (finding “individual members of a plaintiff class, *aside from named representatives*, need not satisfy the “minimum contacts” test in order for a [] forum court to exercise personal jurisdiction over them”) (emphasis added) (citation omitted); *Greene*, 2017 WL 7410565, at *4 (N.D. Ill. Dec. 11, 2017) (finding “that due process requires a connection between the forum and the specific claims at issue. That principle applies with equal force whether or not the plaintiff is a putative class representative.”) (citations omitted); *Wenokur*, 2017 WL 4357916, at *4 (finding it “lacks personal jurisdiction over the claims of putative class members with no connection to Arizona and therefore would not be able to certify a nationwide class”).

***16** While Plaintiffs allege SERVICES and MOBILITY have business locations and employees in New Jersey, they do not allege Larson or Pollard were one of those employees. In fact, Larson is a citizen of the state of Arizona and worked for “AT&T” from her home in Arizona (ECF No. 1 ¶¶ 3, 102-03) and Pollard is a citizen of the state of Florida and worked for “AT&T” from his home in Florida. (*Id.* ¶¶ 5, 181.) Both Plaintiffs received their W-2 from SERVICES, which is incorporated in Delaware and headquartered in Texas. (*Id.* ¶ 15.) Because Larson and Pollard’s claims relate to their employment, the facts giving rise to their claims

in this circumstance could not have arisen in New Jersey. For that reason, there is no specific jurisdiction as to their claims against SERVICES and MOBILITY. Accordingly, SERVICES and MOBILITY's Motion to Dismiss as to Larson and Pollard's claims is **GRANTED**.

B. CORP, SERVICES and MOBILITY's Motion to Dismiss Larson and Seaman's Claims

1. Whether Larson and Seaman Allege Facts Sufficient to Support a Collective Action

CORP, SERVICES and MOBILITY argue Larson and Seaman's class action claims should be dismissed for failure to "give rise to a plausible claim that any unlawful discriminatory practice has affected similarly situated individuals." (ECF No. 22-1 at 7.) Plaintiffs argue CORP, SERVICES, and MOBILITY's Motion to Dismiss is improper at this stage because Plaintiffs have not yet moved to certify the class and because they have sufficiently plead the necessary elements of an ADEA class claim. (ECF No. 41 at 5-6, 9-10.)

In most federal class actions, the issues of joinder among, and notice to, potential class members are governed by **Federal Rules of Civil Procedure 23**. However, class actions brought under the ADEA are governed by Section 7(b) of the ADEA, **29 U.S.C. § 626(b)**, which incorporates certain select provisions of the FLSA, **29 U.S.C. §§ 201 et seq.**, to establish the "powers, remedies, and procedures" by which the ADEA is to be enforced. One of these provisions, **29 U.S.C. § 216(b)**, provides for class actions as follows:

An action to recover the liability prescribed may be maintained against any employer (including a public agency) in any Federal or State court of competent jurisdiction by any one or more employees for and in behalf of himself or themselves and other employees similarly situated. No employee shall be a party plaintiff to any such action unless he gives his consent in writing to become such a party and such consent is filed in the court in which such action is brought.

Therefore, ADEA class actions may only proceed under **29 U.S.C. § 216(b)**, and not under **Rule 23**. See, e.g., *Lusardi v. Xerox Corp.*, 99 F.R.D. 89, 92 (D.N.J. 1983), *app. dismissed*, 747 F.2d 174 (3d Cir. 1984); *LaChapelle v. Owens-Illinois, Inc.*, 513 F.2d 286, 289 (5th Cir. 1975). Section 216(b) creates an "opt-in" mechanism for class formation and **Rule 23** creates an "opt-out" mechanism, and, in the case of the ADEA, the incorporation of the former prohibits application of the latter. *Lusardi*, 99 F.R.D. at 92, *LaChapelle*, 513 F.2d at 289.

Pursuant to **§ 216(b)** an ADEA plaintiff may "maintain" a suit on behalf of itself and other employees once two conditions are met: (1) the named plaintiffs and the other employees must be "similarly situated;" and (2) the other employees must have filed written consents to join the action. *Sperling v. Hoffmann-La Roche, Inc.*, 118 F.R.D. 392, 399 (D.N.J.), *aff'd in part, appeal dismissed in part sub nom.*, 862 F.2d 439 (3d Cir. 1988), *aff'd and remanded sub nom.*, 493 U.S. 165 (1989); *Lusardi*, 99 F.R.D. at 91-92.

Due to the two-stage class certification process in ADEA class actions, there is disagreement among the district courts as to whether dismissal of ADEA collective action allegations under **Rule 12(b)(6)** is proper before a plaintiff has made a motion for conditional class certification under *Lusardi*. A minority of district courts have held that a motion to dismiss is inappropriate to challenge the sufficiency of class allegations when the plaintiffs have not yet moved for conditional certification. *Barrett v. Forest Labs., Inc.*, No. 12-5224, 2014 WL 4058683, at *9 (S.D.N.Y. Aug. 14, 2014); *Lang v. DirecTV, Inc.*, 735 F. Supp. 2d 421, 434-36 (E.D. La. 2010). These courts reason that the "challenge on the pleadings [is an] end-run [around] the certification process," since the plaintiffs have not had the opportunity to develop the record. *Lang*, 765 F. Supp. 2d at 435-36.

***17** The majority of courts have found that a **Rule 12(b)(6)** dismissal of class allegations is appropriate, even when the plaintiff has not yet filed a motion for conditional class certification. See *Zanders v. Wells Fargo Bank, N.A.*, No. 14-00288, 2014 WL 5439298, at *12 (S.D. Iowa Oct. 28, 2014); *Dyer v. Lara's Trucks, Inc.*, No. 12-1785, 2013 WL 609307, at *3 (N.D. Ga. Feb. 19, 2013); *Creech v. Holiday CVS, LLC*, No. 11-46, 2012 WL 4483384, at *2-3 (M.D. La. Sept. 28, 2012). These courts reason that **Rule 12(b)(6)** requires a plaintiff to give the defendant fair notice of the putative class, which is a much different inquiry than the inquiry at the

conditional class certification stage. *Dyer*, 2013 WL 609307, at *3.

Decisions from this District “have made clear that dismissal of class allegations at this sta[g]e should be done rarely and that the better course is to deny such motion because the shape and form of a class action evolves only through the process of discovery.” *Oravsky v. Encompass Ins. Co.*, 804 F. Supp. 2d 228, 241 (D.N.J. 2011) (quoting *Myers v. MedQuist, Inc.*, No. 05-4608, 2006 WL 3751210, at *4 (D.N.J. Dec. 20, 2006) (citing *Gutierrez v. Johnson & Johnson, Inc.*, 2002 WL 34717245, *5 (D.N.J. 2002); *Abdallah v. Coca-Cola Co.*, No. 98-3679, 1999 WL 527835, *1-2 (N.D. Ga. July 16, 1999)); *Landsman & Funk PC v. Skinder-Strauss Assocs.*, 640 F.3d 72, 93 (3d Cir. 2011) (“[Only in a] rare [case does] the complaint itself demonstrate [] that the requirements for maintaining a class action have not been met.”) (other citations omitted).

While in some “rare” cases it may be appropriate pursuant to Rule 12(b)(6) to dismiss class pleadings that are entirely inadequate, this is not such a case. Although the Court is skeptical the facts will show that class resolution is appropriate in this case because Larson and Seaman do not allege that they and all putative collective members were employed by the same AT&T entity, worked in the same department, performed similar work, or had similar circumstances of employment, the Court does find the motion is premature at this stage. *Zavala v. Wal-Mart Stores Inc.*, 691 F.3d 527, 537 (3d Cir. 2012) (stating that factors relevant to whether plaintiffs are similar situated include, but are not limited to “whether the plaintiffs are employed in the same corporate department, division, and location; whether they advance similar claims; whether they seek substantially the same form of relief; and whether they have similar salaries and circumstances of employment”). Indeed, Larson and Seaman have at least alleged they and the potential opt-ins have been injured by a single policy, the 2020 Scheme, which targeted workers over the age of 40. (ECF No. 1 ¶¶ 39–40, 54–88.) Accordingly, CORP, SERVICES and MOBILITY’s Motion to Dismiss Larson and Seaman’s class action claims is **DENIED**.

2. Whether Seaman Waived her Right to Participate in a Collective Action

CORP, SERVICES, and MOBILITY argue Seaman waived her right to participate in a collective action because “she

signed an agreement for good and sufficient consideration that contains a waiver of her right to participate in a collective action.” (ECF No. 22-1 at 12.) Plaintiffs argue Seaman did not waive her right to participate in a collective action because the General Release and Waiver is invalid and unenforceable because it did not comply with the OWBPA and is part of a larger scheme to violate the ADEA. (ECF No. 41 at 17–18.)

*18 Congress amended the ADEA by passing the OWBPA in 1990. *Oubre v. Entergy Operations, Inc.*, 522 U.S. 422, 426 (1998). The OWBPA provides: “An individual may not waive any right or claim under [the ADEA] unless the waiver is knowing and voluntary. [A] waiver may not be considered knowing and voluntary unless at a minimum” it satisfies certain enumerated requirements, including the three listed above. 29 U.S.C. § 626(f)(1) (emphasis added). An employee is considered not to have waived an ADEA claim unless the employer complies with the OWBPA statute. *Oubre*, 522 U.S. at 427. The statutory command of the OWBPA is clear, “[a]n employee ‘may not waive’ an ADEA claim unless the waiver or release satisfies the OWBPA’s requirements.” *Id.* at 426–27.

The policy of the OWBPA is likewise clear from its title: It is designed to protect the rights and benefits of older workers. The OWBPA implements Congress’ policy via a strict, unqualified statutory stricture on waivers, and we are bound to take Congress at its word. Congress imposed specific duties on employers who seek releases of certain claims created by statute. Congress delineated these duties with precision and without qualification: An employee “may not waive” an ADEA claim unless the employer complies with the statute. Courts cannot with ease presume ratification of that which Congress forbids.

Id. at 427. Moreover, “[t]he text of the OWBPA forecloses the employer’s defense, notwithstanding how general contract principles would apply to non-ADEA claims.” *Id.*

Courts have interpreted the phrase “waive any right or claim” under § 626(f)(1) as referring narrowly to waiver of substantive ADEA rights or claims—not procedural rights such as a right to a jury trial or right to proceed as a class action. *See 14 Penn Plaza LLC v. Pyett*, 556 U.S. 247 (2009); *McLeod v. Gen. Mills, Inc.*, 856 F.3d 1160 (8th Cir. 2017). In *14 Penn Plaza LLC*, the Supreme Court addressed the meaning of “rights or claims” under § 626(f)(1)(C), which prohibits waiver of “rights or claims that may arise after the date the waiver is executed.” The Court held that an agreement to bring future claims in arbitration was not a waiver of “rights or claims,” “[t]he decision to resolve ADEA claims by way of arbitration instead of litigation does not waive the statutory right to be free from workplace age discrimination; it waives only the right to seek relief from a court in the first instance.” *14 Penn Plaza*, 556 U.S. at 265–66, 259 (clarifying that an “agreement to arbitrate ADEA claims” is not a waiver of “the ‘right’ referred to in § 626(f)(1)”). Therefore, *14 Penn Plaza* interprets § 626(f)(1)’s references to “right[s] or claim[s]” to mean substantive rights to be free from age discrimination, not procedural “rights” to pursue age discrimination claims in court. *McLeod*, 856 F.3d at 1165.

In *McLeod*, the Eighth Circuit held that § 626(f)’s “‘waiver’ refers narrowly to waiver of substantive ADEA rights or claims—not, as the former employees argue, the ‘right’ to a jury trial or the ‘right’ to proceed in a class action.” *McLeod*, 856 F.3d at 1164. The court reasoned that § 216(b), incorporated by § 626(b), which states, “An action to recover ... liability ... may be maintained ... in any ... court of competent jurisdiction by any one or more employees for and in behalf of himself or themselves and other employees similarly situated,” only “authorizes employees to bring collective age discrimination actions [o]n behalf of ... themselves and other employees similarly situated.” *Id.* at 1165. “Standing alone, § 216(b) does not create a non-waivable substantive right; rather, its class-action authorization can be waived by a valid arbitration agreement.” *Id.* Authorizations of a class action does not create a “right.” *Id.* at 1166.

*19 Here, the General Release and Waiver contains four subsections: (1) Release and Waiver; (2) Non-Interference and Acknowledgement of Payments Received; (3) Class, Collective and Representative Action Waiver; and (4) Older Workers Benefit Protection Act Disclosures. (ECF No. 16–6 at 23–25.) The General Release and Waiver covers ADEA claims:

I understand that there are various local, state and federal laws that govern any employment relationship with the Participating Company and/or prohibit discrimination on the basis of age, color, race, gender, sexual orientation, marital status, national origin, mental or physical disability, religious affiliation or veteran status. Such laws include, but are not limited to, Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, and the Americans with Disabilities Act. By signing this General Release and Waiver, I intend to release any claims I may have under these or any other laws with respect to my employment and to the termination of my employment with the Participating Company.

...

I expressly understand and agree that this is a General Release that, to the fullest extent permitted by law, waives surrenders, and extinguishes all claims that I have or may have against the Released Parties, including but not limited to claims under Title VII of the Civil rights Act of 1964 (title VII), the Civil Rights Act of 1991, the Age Discrimination Act (ADEA) ... PROVIDED, HOWEVER, I am not waiving, releasing or giving up any rights I may have to challenge the knowing and voluntary nature of this General Release and Waiver under the Older Workers benefit Protection Act (OWBPA).

(*Id.* at 23–24.) The Class, Collective and Representative Action Waiver states:

Without limiting the generality of the forgoing, I agree that I will not bring, maintain or participate in any class action, collective action or representative action against any of the Companies which asserts, in whole or in part, any claim(s) which arose prior to the date I sign this Agreement, whether or not such claims are covered by this General Release and Waiver. I further agree that if I am included within a class, collective, or representative action, I will take all steps necessary to opt-out of the action

or refrain from opting in, as the case may be.

(*Id.* at 24.) Therefore, the General Release and Waiver clearly attempts to waive Plaintiffs' ADEA claims, and must comply with the OWBPA.

Even assuming, as the Court must for purposes of this Motion to Dismiss, that the General Release and Waiver did not satisfy the specific requirements of the OWBPA, Seaman only retains the right to bring an individual ADEA action against Defendants. The remaining portions of the General Release and Waiver remain enforceable, such as the Class, Collective and Representative Action Waiver. *See Oubre, 522 U.S. at 427–28* (“Since Oubre’s release did not comply with the OWBPA’s stringent safeguards, it is unenforceable against her insofar as it purports to waive or release her ADEA claim.”); *Brinker v. Pfizer, Inc., 981 F. Supp. 862, 867 (S.D.N.Y. 1997)* (stating that noncompliance with the minimum requirements of the OWBPA would only “invalidate a release of those claims ... failure to comply with the OWBPA cannot invalidate release of ... claims under the NYCHRL and NYSHRL claims, as well as the claim of intentional infliction of emotional distress”). Because § 626(f)’s “waiver” refers only to waiver of substantive ADEA rights or claims—not the “right” to proceed in a class action, Seaman’s collective action allegations are dismissed because she waived her rights to pursue them.

*20 Plaintiffs reliance on *Oubre* and *Hoffmann-La Roche Inc. v. Sperling*, 493 U.S. 165 (1989) for the proposition that the class action provision in unenforceable is misplaced. In fact, in *Oubre*, the Supreme Court held that a waiver of substantive rights to bring an ADEA claim was invalid because it did not comply with the OWBPA’s waiver requirements. *Oubre, 522 U.S. at 428*. In *Hoffmann-La Roche*, the Supreme Court held that district courts have the discretion in ADEA actions to facilitate notice to potential plaintiffs’ and that plaintiffs can discover the names and addresses of discharged employees. *Hoffmann-La Roche Inc. v. Sperling*, 493 U.S. at 174. Neither decision found that the OWBPA’s waiver requirements applied to procedural rights.

Plaintiffs further argue the Court should not dismiss Seaman’s class action claims because the waiver was fraudulent and part of an illegal scheme. (ECF No. 41 at 25–26.) However, other than those bare bone allegations, Plaintiffs fail to articulate any facts demonstrating the remainder of the General Release

and Waiver was entered into involuntarily or unknowingly or was unconscionable. Accordingly, CORP, SERVICES, and MOBILITY’s Motion to Dismiss Seaman’s class action claims is **GRANTED**. As such, Larson may proceed with her class action claims, but Seaman may only proceed individually.

3. Declaratory Judgment that Defendants Violated the OWBPA (Count III)

CORP, SERVICES and MOBILITY argue Count III of the Complaint, declaratory judgment stating that Defendants violated the OWBPA by failing to procure a valid release of Plaintiffs’ ADEA claims should be dismissed because the OWBPA does not authorize an independent cause of action. (ECF No. 22–1 at 13.) In the alternative, they argue the Court should dismiss Count III for lack of standing because no Article III case or controversy arises when a plaintiff seeks a declaratory judgment as to the validity of a defendant that a defendant may or may not use. (ECF No. 45 at 10.) Plaintiffs claim “aggrieved individuals have the right to seek equitable relief in the form of a declaratory judgment and related injunction regarding violations of the OWBPA.” (ECF No. 41 at 12.)

At least one Court in this District has determined that “[u]nder the OWBPA, Plaintiffs are entitled to no ‘affirmative relief, other than *declaratory or injunctive* relief to negate the validity of the waiver, as it applies to an ADEA claim.’” *Al-Farook v. Marina Dist. Dev. Co., LLC*, No. 13–138, 2013 WL 6177933, at *3 (D.N.J. Nov. 25, 2013) (emphasis added) (quoting *Whitehead v. Oklahoma Gas & Elec. Co.*, 187 F.3d 1184, 1191 (10th Cir. 1999); accord *Krane v. Capital One Servs.*, 314 F. Supp. 2d 589, 609–10 (E.D. Va. 2004)). Here, Plaintiffs seek declaratory relief stating the OWBPA was violated. The Court agrees with this District’s precedent and will not delve into the statutory construction arguments articulated by CORP, SERVICES, and MOBILITY in their brief and at oral argument. (See ECF No. 22–1 at 14.) To the extent Plaintiffs seek anything other than a declaratory judgment and seek secondary relief, including attorney’s fees and various other legal and equitable remedies, they are not entitled to such. *Al-Farook*, 2013 WL 6177933, at *3. They are only entitled to “declaratory or injunctive relief to negate the validity of the waiver, as it applies to an ADEA claim.” *Id.* Nevertheless, this argument is irrelevant because the Court lacks jurisdiction over Count III.

The Court finds it lacks jurisdiction over Count III because there is no Article III case or controversy. “Article III of the Constitution limits the jurisdiction of federal courts to ‘Cases’ and ‘Controversies.’ ” *Lance v. Coffman*, 549 U.S. 437, 439 (2007). “Standing to sue is a doctrine rooted in the traditional understanding of a case or controversy.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). “The standing inquiry focuses on whether the party invoking jurisdiction had the requisite stake in the outcome when the suit was filed.” *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 360 (3d Cir. 2014) (citing *Davis v. FEC*, 554 U.S. 724, 734 (2008)).

*21 Article III “standing consists of three elements.” *Spokeo*, 136 S. Ct. at 1547 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). To establish standing, “[t]he plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Id.* “The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements.” *Id.* (citing *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990)).

As in *Spokeo*, “[t]his case primarily concerns injury in fact, the ‘[f]irst and foremost’ of standing’s three elements.” *Id.* (quoting *Steel Co. v. Citizens for Better Env’t*, 523 U.S. 83, 103 (1998)). “To establish injury in fact, a plaintiff must show that he or she suffered ‘an invasion of a legally protected interest’ that is ‘concrete and particularized’ and ‘actual or imminent, not conjectural or hypothetical.’ ” *Id.* at 1548 (quoting *Lujan*, 504 U.S. at 560). “For an injury to be ‘particularized,’ it ‘must affect the plaintiff in a personal and individual way.’ ” *Id.* (citations omitted). “Particularization is necessary to establish injury in fact, but it is not sufficient. An injury in fact must also be ‘concrete.’ ” *Id.* “A ‘concrete’ injury must be ‘de facto’; that is, it must actually exist.” *Id.* (explaining that “[w]hen we have used the adjective ‘concrete,’ we have meant to convey the usual meaning of the term—‘real,’ and not ‘abstract’ ”). “Concreteness, therefore, is quite different from particularization.” *Id.*

In *McLeod*, thirty-three plaintiffs who signed releases requested declaratory judgment that the releases were not knowing and voluntary, even though the employer had not threatened or attempted to enforce the ADEA waiver. *McLeod*, 856 F.3d at 1163, 1166–67. The court held:

An Article III case or controversy may exist where a private party

threatens an enforcement action that would cause an imminent injury. Here, though, the former employees do not plead that General Mills threatens any enforcement of the ADEA claim waiver, let alone enforcement that would cause them imminent injury. Instead, they request a declaration of their rights under a hypothetical set of facts. They want to know their legal rights if, in the future, General mills asserts that the waivers of their substantive ADEA rights were “knowing and voluntary” under § 626(f)(3).

It further concluded “[n]o Article III case or controversy arises when plaintiffs seek ‘a declaratory judgment as to the validity of a defense’ that a defendants ‘may, or may not, raise’ in a future proceeding.” *Id.* at 1167 (quoting *Calderon v. Ashmus*, 523 U.S. 740, 747 (1998)).

Here, much like the case in *McLeod*, Plaintiffs do not plead that CORP, SERVICES, and MOBILITY threaten enforcement of the ADEA claim waiver. They too request a declaration of their rights under a hypothetical set of facts, as if CORP, SERVICES, and MOBILITY invoked the defense. As such, the Court does not have jurisdiction over Plaintiffs’ declaratory judgment claims. Accordingly, CORP, SERVICES, and MOBILITY’s Motion to Dismiss Count III of the Complaint is **GRANTED**.

4. Collective Disparate Impact Claim (Count II)

CORP, SERVICES, and MOBILITY argue Plaintiffs’ collective disparate impact claim should be dismissed because they do not identify a specific, facially neutral practice or policy. (ECF No. 22–1 at 17–21.) Plaintiffs argue they can proceed under a disparate impact or disparate treatment theory because the Complaint alleges a specific facially neutral policy. (ECF No. 41 at 27.)

*22 A plaintiff’s initial burden is heavier under a disparate impact theory than it is under a disparate treatment theory. *Massarsky v. Gen. Motors Corp.*, 706 F.2d 111, 120 (3d Cir.), cert. denied, 464 U.S. 937 (1983); *Bratke—v. TD Bank, N.A.*, No. 11–3049, 2012 WL 603299, at *6 (D.N.J. Feb. 22, 2012)

(citing *Cherchi v. Mobil Oil Corp.*, 693 F. Supp. 156, 166 (D.N.J. 1988) *aff'd*, 865 F.2d 249 (3d Cir. 1988)). “To state a *prima facie* case for disparate impact under the ADEA, a plaintiff must (1) identify a specific, *facially neutral* policy, and (2) proffer statistical evidence that the policy caused a significant age-based disparity.” *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 69 (3d Cir. 2017) (citing *NAACP v. N. Hudson Reg'l Fire & Rescue*, 665 F.3d 464, 476–77 (3d Cir. 2011)). If a plaintiff establish a *prima facie* case, “an employer can defend by arguing that the challenged practice was based on ‘reasonable factors other than age’—commonly referred to as the ‘RFOA’ defense.” *Id.* (citing 29 U.S.C. § 623(f)(1); 29 C.F.R. § 1625.7).

Although a plaintiff need not establish discriminatory motive or intent under a disparate impact theory, proof of actual discrimination is a necessary element. Plaintiffs must show that a *facially neutral* standard resulted in a significantly discriminatory pattern or impact. *Bryant v. Int'l Sch. Sers., Inc.*, 675 F.2d 562, 572 (3d. Cir. 1982) (citations omitted). To plead a disparate impact claim under the ADEA, “it is not enough to simply allege that there is a disparate impact on workers, or point to a generalized policy that leads to such an impact. Rather, the employee is responsible for isolating and identifying the specific employment practices that are allegedly responsible for any observed statistical disparities.” *Smith v. City of Jackson Miss.*, 544 U.S. 228, 241 (2005) (internal citations omitted). Moreover, the plaintiff must show that the “*facially neutral* employment practice had a significantly discriminatory impact.” *Connecticut v. Teal*, 457 U.S. 440, 446 (1982). Statistical evidence of this impact “must be limited in scope in accordance with [Federal Rule of Civil Procedure] 26(b)(1) and tied to the allegations of plaintiff’s complaint.” *Kresefky v. Panasonic Commc’ns & Sys. Co.*, 169 F.R.D. 54, 66 (D.N.J. 1996). Although

there is no ‘rigid mathematical formula’ courts can mandate or apply to determine whether plaintiffs have established a *prima facie* case ... a plaintiff will typically have to demonstrate that the disparity in impact is sufficiently large that it is highly unlikely to have occurred at random, and to do so by using one of several tests of statistical significance.

Petruska v. Reckitt Benckiser, LLC, No. 14–03663, 2015 WL 9582142, at *3 (D.N.J. Dec. 29, 2015) (quoting *Stagi v. Nat'l R.R. Passenger Corp.*, 391 Fed.Appx. 133, 137 (3d Cir. 2010) (internal citations omitted)).

Here, Plaintiffs fail to identify a specific, *facially neutral* policy. Instead, they plead Defendants implemented an intentionally bias 2020 Scheme. (See ECF No. 1 ¶ 42 (“AT&T maintains a corporate culture of age discrimination that emanates from the highest levels of the company.”); ¶ 51 (“As part of its company-wide ‘2020’ plan to transform its aging workforce, AT&T has for several years conducted vast involuntary group terminations with the intent and effect of eliminating older workers from its workforce.”); ¶ 56 (“AT&T’s three-step ‘surplus,’ then termination and fraudulent release scheme is infected with age bias.”).) Courts have held that such allegations amount to a claim for disparate treatment—not disparate impact. See *Maresco v. Evans Chemetics, Div. of W.R. Grace & Co.*, 964 F.2d 106, 115 (2d Cir. 1992) (stating that “allowing the disparate impact doctrine to be invoked as [the plaintiff] proposes would simply provide a means to circumvent the subject intent requirement in any disparate treatment case.”); *Zawacki v. Realogy Corp.*, 628 F. Supp. 2d 274, 281 (D. Conn. 2009) (“Plaintiff alleges that the Defendant’s procedure in conducting the RIFs were nothing more than a cover for behind-the-scenes, intentional dissemination against its older employees. There is no allegation of a *facially neutral* practice or policy that fell more harshly on the protected group.”). As such, “where the employment practices support the Plaintiff’s disparate impact claims are the employment practices supporting the disparate treatment claims,” they should be dismissed because “it provides a means for the Plaintiff to avoid establish the subjective intent requirement for her disparate treatment claims.” *Zawacki*, 628 F. Supp. 2d at 281 n.4. Accordingly, CORP, SERVICES, and MOBILITY’s Motion to Dismiss Count II of the Complaint as it applies to collective disparate impact is **GRANTED**.

IV. CONCLUSION

*23 For the reasons set forth above: (1) INC’s Motion to Dismiss for lack of jurisdiction is **DENIED**; (2) SERVICES and MOBILITY’s Motion to Dismiss Larson and Pollard’s claims for lack of jurisdiction is **GRANTED**; (3) and CORP, SERVICES, and MOBILITY’s Motion to Dismiss for failure to state a claim is **DENIED** as to the class action claims and **GRANTED** as to all other requests.

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TAB 24

2017 WL 3971912

 KeyCite Yellow Flag - Negative Treatment

Disagreed With by [Debernardis v. IQ Formulations, LLC](#), 11th Cir.(Fla.), November 14, 2019

2017 WL 3971912

Only the Westlaw citation is currently available.
United States District Court, W.D. Pennsylvania.

Daniel HUBERT, individually and on behalf
of all others similarly situated, Plaintiff,

v.

GENERAL NUTRITION
CORPORATION, Defendant.

2:15-cv-01391

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Signed 09/08/2017

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OPINION

Mark R. Hornak, United States District Judge

*1 Presently before the Court is a motion by Defendant General Nutrition Corporation (“GNC” or “Defendant”) to dismiss the First Amended Consolidated Class Action Complaint (the “Amended Complaint”) filed by Plaintiff Daniel Hubert, individually and on behalf of similarly situated individuals (ECF No. 39) pursuant to [Federal Rules of Civil Procedure 12\(b\)\(1\) and 12\(b\)\(6\)](#) (the “Motion to Dismiss”) (ECF No. 48). In this prospective class action litigation, Plaintiff Hubert alleges that he and other consumers (“Plaintiffs”) purchased supplements sold by GNC with false and misleading labeling in violation of the Magnuson-Moss Warranty Act, [15 U.S.C. § 2301, et seq.](#), and the consumer fraud protection laws of numerous states.¹ Plaintiffs further assert that GNC breached implied warranties, engaged in

negligent misrepresentation and unjustly enriched itself to the detriment of consumers. Defendant has moved to dismiss the Amended Complaint for lack of subject matter jurisdiction and for failure to state a claim. For the reasons set forth below, Defendant’s Motion to Dismiss for lack of subject matter jurisdiction will be granted, and the Amended Complaint will be dismissed, without prejudice.² Because the Court finds that Plaintiffs lack standing to bring this case, it need not address Defendant’s other theories.

¹ Plaintiffs allege that GNC violated the following state laws: Arkansas’s Deceptive Trade Practice Act, [Ark. Code Ann. § 4-88-101, et seq.](#); California’s Unfair Competition Law, [Cal. Bus. & Prof. Code § 17200, et seq.](#); California’s Consumer Legal Remedies Act, [Cal. Civ. Code § 1750, et seq.](#); California’s False Advertising Law, [Cal. Bus. & Prof. Code § 17500, et seq.](#); Florida’s Deceptive and Unfair Trade Practices Act, [Fla. Stat. § 501.201, et seq.](#); Iowa’s Private Right of Action for Consumer Frauds Act, Iowa Code Ch. 714H; Michigan’s Consumer Protection Act, [Mich. Comp. Laws Ann. § 445.901, et seq.](#); Minnesota’s Unlawful Trade Practices Act, [Minn. Stat. Ann. § 325D.09, et seq.](#); Minnesota’s Uniform Deceptive Trade Practices Act, [Minn. Stat. Ann. § 325D.43, et seq.](#); Minnesota’s Consumer Fraud Act, [Minn. Stat. Ann. § 325F.68, et seq.](#); Minnesota’s False Statement in Advertising Act, [Minn. Stat. Ann. § 325F.67](#); Minnesota’s Private Attorney General Statute, [Minn. Stat. Ann. § 8.31, et seq.](#); New York’s General Business Law, [N.Y. Gen. Bus. Law § 349](#); New Hampshire’s Consumer Protection Act, N.H. Rev. Stat. Ann. § 358-A, *et seq.*; Pennsylvania’s Unfair Trade Practices and Consumer Protection Law, [73 P.S. § 201-1, et seq.](#); and Texas’ Deceptive Trade Practices-Consumer Protection Act, [Tex. Bus. & Com. Code Ann. § 17.41, et seq.](#)

² In view of the Court’s ruling granting the Motion to Dismiss for lack of subject matter jurisdiction, Defendant’s Request for Judicial Notice (ECF No. 49-5) and Plaintiffs’ Motion to Strike Declaration of Stephen Cherry (ECF No. 59) will be denied as moot.

I. BACKGROUND

GNC, which is headquartered in Pittsburgh, Pennsylvania, is the largest global specialty retailer of [nutritional supplements](#). Am. Compl. ¶¶ 25, 36. Plaintiffs allege that GNC marketed and sold supplements manufactured by third party vendors, which allegedly contained picamilon, BMPEA or acacia rigidula, despite having known that these substances are not dietary ingredients.³ Id. ¶¶ 3, 4, 38. The supplements at issue here are primarily weight-loss and sports nutrition supplements available as powders and liquids. Id. ¶ 27.

³ Picamilon is a synthetic chemical which is used as a prescription drug in Russia, but it is not approved as a drug in the United States, BMPEA is an amphetamine-like chemical that is not found in nature, acacia rigidula is an herb or other botanical, and both BMPEA and acacia rigidula allegedly have no history of safe use. Am. Compl. ¶¶ 4, 39, 48, 66.

*2 Plaintiffs aver that federal and state law place primary responsibility for the safety of dietary supplements,⁴ as well as truthful labeling and advertising, on supplement manufacturers and distributors such as GNC. Am. Compl. ¶ 28. According to Plaintiffs, GNC sold products with false and misleading labeling, and it failed to disclose material facts about the dangers of ingesting picamilon, BMPEA and acacia rigidula. Id. ¶ 5. Plaintiffs claim that they were “hoodwinked” into purchasing supplements containing these substances and would not have done so if GNC had disclosed that they contained mislabeled ingredients which purportedly pose serious health risks and are not marketable as dietary supplements. Id. ¶¶ 6, 24.

⁴ A dietary supplement is a product intended to supplement the diet that contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; or a combination thereof. Am. Compl. ¶ 29. A dietary ingredient that was not previously marketed in the United States prior to October 14, 1994, is considered a “new dietary ingredient” (“NDI”). Id. ¶ 30. A manufacturer is required to notify the FDA if it intends to market a supplement that contains a NDI. Id. ¶ 31. If the FDA does not comment within 75 days after the NDI submission, the ingredient may be used in dietary supplements. Id.

Regarding picamilon, Plaintiffs allege that Jennifer Jakel (“Jakel”), who was GNC’s Senior Project Manager for

Technical Research, reviewed documents translated from Russian indicating that it is a “derivative of gamma-aminobutyric acid and nicotinic acid.” Am. Compl. ¶ 43. In 2007, Jakel made a notation stating “[n]o NDI that I could find,” suggesting that a NDI submission was not tendered to the Food and Drug Administration (“FDA”) for picamilon. Id. ¶¶ 31, 44. Again in April 2014, Jakel wrote “still no NDI found.” Id. ¶ 44.

Subsequently, on September 28, 2015, Dr. Cara Welch of the FDA issued a declaration stating that “picamilon does not qualify as a dietary ingredient” under the Food, Drug and Cosmetic Act (the “FDC Act”). Am. Compl. ¶ 40. Plaintiffs allege that GNC continued to sell dietary supplements containing picamilon until September 21, 2015, despite having known since 2007 that it was not a dietary ingredient. Id. ¶¶ 44, 46.

Plaintiffs additionally claim that GNC has been aware since the fall of 2013 that some dietary supplements labeled as containing acacia rigidula actually contained BMPEA. Am. Compl. ¶¶ 52. Ms. Jakel supposedly was notified in November 2013 of a study by FDA researchers which revealed that many dietary supplements purportedly containing acacia rigidula actually contained BMPEA, despite no testing to show that BMPEA was safe for humans (hereinafter, “the FDA Study”). Id. ¶¶ 49, 52. Subsequently, Jakel allegedly emailed a *USA Today* article about the FDA Study to approximately 100 recipients at GNC. Id. ¶ 52.

Plaintiffs allege that despite knowing of the FDA Study, GNC continued to sell supplements containing acacia rigidula, without testing them to determine whether they were adulterated with BMPEA. Am. Compl. ¶¶ 55. However, in April 2015, when the FDA formally announced that BMPEA did not meet the definition of a dietary ingredient, GNC stopped selling products containing BMPEA. Id. ¶ 60.

Concerning acacia rigidula, Plaintiffs allege that the FDA warned six manufacturers in March 2016, that it is a new dietary ingredient which lacks evidence of safe use and therefore could not be lawfully sold in the United States. Am. Compl. ¶ 67. Plaintiffs allege that GNC did not provide the FDA with the required pre-market notification showing a history of acacia rigidula’s safe use, yet it was openly found on labels of supplements offered for sale at GNC. Id. ¶¶ 70, 72.

*3 Plaintiffs aver that despite GNC's alleged knowledge regarding picamilon, BMPEA and acacia rigidula, GNC sold products containing those substances which were supplied by third-party vendors. Am. Compl. ¶ 78. Plaintiffs claim that GNC exercised significant control over the third-party products it sold by reviewing and pre-approving labels, warnings, packaging and advertising. *Id.* ¶¶ 73, 74. In addition, third-party vendors could not alter approved formulas, labels or advertising without GNC's permission. *Id.* ¶ 74. By controlling the product labels of third party vendors, Plaintiffs allege that GNC misrepresented that supplements containing picamilon, BMPEA and acacia rigidula were safe for consumers and legal to sell. *Id.* ¶ 79. According to Plaintiffs, it is irrelevant that GNC received guarantees from third-party vendors that products containing those substances complied with legal requirements because GNC knew or should have known that they were not safe and could not be lawfully sold. *Id.* ¶¶ 75, 76.

In sum, Plaintiffs allege that picamilon, BMPEA and acacia rigidula were listed on the labels of a variety of supplements available for sale at GNC, including products that they purchased. Am. Compl. ¶¶ 47, 65, 72. Plaintiffs claim that through this labeling, GNC misrepresented that those substances were safe and could be legally sold in the United States. *Id.* As a result, Plaintiffs assert that they purchased supplements they otherwise would not have purchased, paid more for supplements than they otherwise would have paid and have been subjected to unreasonable safety risks. *Id.* ¶¶ 6, 24, 81.

II. STANDARD OF REVIEW

Under Fed.R.Civ.P. 12(b)(1), "a court must grant a motion to dismiss if it lacks subject-matter jurisdiction to hear a claim." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012). "A motion to dismiss for want of standing is ... properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter." *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007).

In evaluating a challenge to subject matter jurisdiction under Rule 12(b)(1), a court first must determine whether the movant presents a facial or a factual attack. See *Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). The distinction is important because it determines how the complaint must be reviewed. See *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). A facial attack "challenges subject matter jurisdiction without disputing the facts alleged in the complaint, and it requires the court

to 'consider the allegations of the complaint as true.' " *Davis*, 824 F.3d at 346 (citation omitted). A factual challenge "attacks the factual allegations underlying the complaint's assertion of jurisdiction, either through the filing of an answer or 'otherwise present[ing] competing facts.' " *Id.* (citation omitted). Here, GNC makes a facial challenge because it has not disputed the validity of Plaintiffs' factual claims in its Motion to Dismiss. In essence, GNC contends that the allegations of the Amended Complaint, even accepted as true, are insufficient to establish Plaintiffs' Article III standing.

In considering a facial challenge to standing, courts are to apply the same standard as on review of a Rule 12(b)(6) motion for failure to state a claim. See *Petruska v. Gannon Univ.*, 462 F.3d 294, 299 n.1 (3d Cir. 2006) (explaining "that the standard is the same when considering a facial attack under Rule 12(b)(1) or a motion to dismiss for failure to state a claim under Rule 12(b)(6)" (citation omitted)). Consequently, the court is to "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff [has standing]." *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (citation omitted). Nonetheless, "[t]hreadbare recitals of the elements of [standing], supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Thus, "[t]o survive a motion to dismiss [for lack of standing], a complaint must contain sufficient factual matter" that would establish standing if accepted as true. *Id.* (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

III. DISCUSSION

*4 GNC argues that the Amended Complaint must be dismissed for lack of standing because Plaintiffs have not sufficiently pled the essential element of injury-in-fact. According to GNC, Plaintiffs simply allege that they purchased the supplements, but do not allege that they actually consumed them or suffered any adverse health consequences from them. GNC points out that any apprehension Plaintiffs may have about possible future injury is insufficient to establish injury-in-fact.

Plaintiffs respond that they have suffered an economic injury, which suffices to establish injury-in-fact for standing purposes. Plaintiffs contend that they incurred economic injury because they purchased products with false, misleading and inaccurate labeling, which omitted information material to their purchases.

GNC counters that the gravamen of the Amended Complaint involves picamilon, BMPEA and acacia rigidula purportedly endangering the health of consumers. GNC contends that despite the emphasis on the alleged health dangers posed by those substances, Plaintiffs attempt to shift the focus to economic injury in order to establish an injury-in-fact for standing purposes. Even so, GNC urges that Plaintiffs have not sufficiently pled the element of injury-in-fact because they do not allege they purchased the supplements after the FDA issued warning letters.

For reasons explained below, the Court agrees that an economic injury can qualify as an injury-in-fact for standing purposes, but concludes that Plaintiffs have not adequately alleged that they suffered an injury-in-fact in this case. Therefore, the Amended Complaint must be dismissed for lack of standing.

A. Article III Standing

Article III of the Constitution limits the scope of federal judicial power to the adjudication of “cases” or “controversies.” U.S. Const., art. III, § 2. “The courts have developed several justiciability doctrines to enforce the case-or-controversy requirement, and perhaps the most important of these doctrines is the requirement that a litigant have standing to invoke the power of a federal court.” [In re Schering Plough](#), 678 F.3d at 244 (internal quotations and citation omitted). “[T]he standing question is whether the plaintiff has ‘alleged such a personal stake in the outcome of the controversy’ as to warrant his invocation of federal-court jurisdiction and to justify exercise of the court’s remedial powers on his behalf.” [Warth v. Seldin](#), 422 U.S. 490, 498-99 (1975) (quoting [Baker v. Carr](#), 369 U.S. 186, 204 (1962)).

It is well established that the “irreducible constitutional minimum” of standing consists of three elements. [Lujan v. Defenders of Wildlife](#), 504 U.S. 555, 560 (1992). “The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” [Spokeo, Inc. v. Robins](#), 136 S.Ct. 1540, 1547 (2016) (citing [Lujan](#), 504 U.S. at 560-61). The plaintiff, as the party invoking federal jurisdiction, bears the burden to establish standing. [Lujan](#), 504 U.S. at 561. At the pleading stage, the plaintiff must “clearly ... allege facts demonstrating” each element. [Spokeo](#), 136 S.Ct. at 1547 (quoting [Warth](#), 422 U.S. at 518).

Although there are three required elements of constitutional standing, the Third Circuit has emphasized that “the injury-in-fact element is often determinative.” [Toll Bros., Inc. v. Twp. of Readington](#), 555 F.3d 131, 138 (3d Cir. 2009); see also [Spokeo](#), 136 S.Ct. at 1547 (observing that injury-in-fact is the “[f]irst and foremost” of standing’s three elements) (citation omitted). To establish injury-in-fact, a plaintiff must show that he suffered “an invasion of a legally protected interest” that is “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” [Lujan](#), 504 U.S. at 560. Although “[i]njury-in-fact is not Mount Everest,” [Danvers Motor Co., Inc. v. Ford Motor Co.](#), 432 F.3d 286, 294 (3d Cir. 2005), the complaint still must “clearly and specifically set forth facts sufficient to satisfy” Article III standing requirements. [Whitmore v. Arkansas](#), 495 U.S. 149, 155 (1990).

*5 The Third Circuit has explained that “[w]hile it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms.” [Danvers Motor](#), 432 F.3d at 291. Indeed, “[m]onetary harm is a classic form of injury-in-fact.” [Id.](#) at 293 (citation omitted). However, allegations of “possible future injury” are insufficient to satisfy the requirements of Article III. [Whitmore](#), 495 U.S. at 158; [Reilly v. Ceridian Corp.](#), 664 F.3d 38, 42 (3d Cir. 2011).

B. Plaintiffs Have Not Established That They Suffered an Injury-in-Fact, Thus They Lack Standing.

Plaintiffs are correct that economic injury can suffice to establish injury-in-fact for standing purposes. However, the question here is whether Plaintiffs have suffered an economic injury. The Court concludes that the Amended Complaint does not adequately plead facts that establish they have; consequently, Plaintiffs have not established that they suffered an injury-in-fact.

1. Analysis of Injury-In-Fact

The Court’s standing analysis is informed by precedent from courts within this Circuit that have evaluated whether the plaintiff suffered an injury-in-fact in cases where, as here, it was alleged the product at issue contained a dangerous substance that was unknown to the consumer or the product label contained alleged misrepresentations.⁵

⁵ The Court is cognizant that Plaintiffs cite cases from other jurisdictions to support their position

2017 WL 3971912

that they have suffered an economic injury. See Plaintiffs' Resp. in Opp'n (ECF No. 61 at 6, n.3). As stated, however, the Court relies on the precedent from the Third Circuit discussed herein to assess whether the Plaintiffs have sufficiently established an injury-in-fact for standing purposes.

First, in Koronthaly v. L'Oreal USA, Inc., 374 Fed.Appx. 257 (3d Cir. 2010), our Court of Appeals affirmed a district court's dismissal for lack of standing in a case where the plaintiff purchased lipstick that contained lead, which was not disclosed on the packaging or the product, and the plaintiff claimed she would not have purchased the lipstick had she known about the lead. In finding no standing, the Third Circuit deemed it significant that the plaintiff conceded she suffered no adverse health consequences from using the lipstick, and her subjective allegation that trace amounts of lead in the lipstick were unacceptable to her was not an injury-in-fact. Id. at 259. Further, to the extent the plaintiff claimed that the injury-in-fact was the loss of the "benefit of the bargain," the Third Circuit explained that she mistakenly relied on contract law. Id. Because the plaintiff's lipstick purchases were not made pursuant to a contract, she could not have been denied the benefit of any bargain. Id. The Third Circuit concluded that "[a]bsent any allegation that [the plaintiff] received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect, [she] has not demonstrated a concrete injury-in-fact." Id.

In Young v. Johnson & Johnson, Civil Action No. 11-4580, 2012 WL 1372286 (D.N.J. Apr. 19, 2012), the district court determined that the plaintiff lacked standing in a case involving the alleged misrepresentation of the nutritional content and health benefits of Benecol, a butter/margarine substitute. The court found that the plaintiff did not sufficiently plead an injury-in-fact because he merely alleged that he purchased Benecol fairly regularly during a five-year period, but he did not allege that he actually consumed it or that he suffered any adverse health effects from it. Id. at *3. In addition, the court found unavailing the plaintiff's contention that he satisfied the injury-in-fact requirement based on allegations that he was deprived of the "benefit of the bargain," received an inferior product and paid a premium price because he believed Benecol was healthy, when in fact it was not. Id. at *4. In finding no economic injury, the court explained that the plaintiff's purchases of Benecol were not made pursuant to a contract and he did not allege how he paid a premium for it or received a product that did not deliver

the advertised benefits. Id. (citing Koronthaly, 374 Fed.Appx. 259).

*6 In both James v. Johnson & Johnson Consumer Cos., Inc., Civil No. 10-cv-03049, 2011 WL 198026 (D.N.J. Jan. 20, 2011) and Medley v. Johnson & Johnson Consumer Cos., Inc., Civil No. 10-cv-02291, 2011 WL 159674 (D.N.J. Jan. 18, 2011), the district court accepted the plaintiffs' contention that economic injury suffices to confer standing, but found that they could not clear the threshold requirement for showing an economic injury. The cases involved ten plaintiffs who alleged Johnson & Johnson violated the FDA's ban on methyl chloride in cosmetic products because its baby shampoo contained that substance. The economic injury for which the plaintiffs sought redress was the price they paid for the shampoo, which the court noted they apparently used in bathing their children without adverse health reactions. Id. at *2. The court accepted as true the plaintiffs' allegation that had they known the true nature of the baby shampoo, they would not have purchased it or allowed their children to be exposed to it, but determined that economic damages did not follow as a consequence. Id. The court concluded that once the shampoo had been used, there was no economic injury for the plaintiffs to complain of and the fear of future injury is insufficient to confer standing. Id. The court observed that the plaintiffs received the benefit of their bargain so long as there were no adverse health effects and the shampoo worked as intended, meaning that it cleansed the children's hair without producing irritation, and nothing in the complaint suggested otherwise. Id. As such, the court found that the plaintiffs did not demonstrate that they suffered an injury-in-fact.

Likewise, in Estrada v. Johnson & Johnson, Civil Action No. 16-7492, 2017 WL 2999026 (D.N.J. July 14, 2017), the court found that the plaintiff did not suffer an injury-in-fact and therefore lacked standing. In that case, the plaintiff asserted California state law consumer-fraud claims against Johnson & Johnson, claiming that it had been aware since at least 1982 of studies associating talcum powder with an elevated risk of ovarian cancer for women, yet failed to disclose that risk to consumers and continued to market baby powder as safe despite knowledge of the risk. As a result of Johnson & Johnson's misrepresentations and omissions, the plaintiff claimed to have suffered an economic injury based on three theories: (1) benefit of the bargain; (2) alternative product; and (3) premium price. Id. at * 6.

First, the plaintiff claimed that she did not receive the benefit of her bargain because she purchased baby powder under the

2017 WL 3971912

belief that it was safe, but she would not have done so had she known that using baby powder in the genital area could lead to an increased risk of developing ovarian cancer. Estrada, 2017 WL 2999026, at *6. The court ultimately found that the plaintiff did not suffer an economic injury-in-fact based on a benefit of the bargain theory. Id. at *13. The court noted that the plaintiff's claim was similar to those alleged by the consumers in Koronthaly, James and Medley: she alleged that she used baby powder; it was effective for its intended uses of eliminating friction and absorbing excess moisture; she was not physically injured; Johnson & Johnson failed to list enough warnings about an alleged increased risk of ovarian cancer associated with baby powder use; and she would like her money back. Id. at *9. However, the court found that absent a plausible allegation of adverse health consequences from using baby powder or that it failed to perform satisfactorily for its intended use, the plaintiff could not claim that she was denied the benefit of her bargain.⁶ Id. (citing Koronthaly, 374 Fed.Appx. at 259; James, 2011 WL 198026, at *2). The court held that the plaintiff's benefit of the bargain theory, based on Johnson & Johnson's alleged omissions, was an insufficient basis to find that she suffered an injury-in-fact. Id. at *9, 13. If the plaintiff wanted to file an amended complaint to reassert a benefit of the bargain theory, the court required that she point to an affirmative legal duty on Johnson & Johnson's part to disclose the facts that allegedly were omitted. Id. at *9.

⁶

The Estrada court distinguished cases cited by the plaintiff which recognized standing on a benefit of the bargain theory of economic harm, explaining that the plaintiffs in those cases did not receive the benefit of their bargain because either: (1) they received a defective product; or (2) they pled facts sufficient for the court to conclude that they were induced into purchasing the product at issue based on a specific misrepresentation made by the defendants. See Estrada, 2017 WL 2999026, at *9-*11 (citations omitted). Unlike the consumers in those cases, the plaintiff in Estrada did not sufficiently allege that she was induced into purchasing baby powder based on specific misrepresentations made by Johnson & Johnson on its website, or on the product's label or advertisements. Id. at *11.

*7 Next, the Estrada court found that the plaintiff did not establish that she suffered an injury-in-fact under an alternative product theory of economic harm. Estrada, 2017

WL 2999026, at * 14. The court recognized that injury-in-fact exists where a consumer alleges that, absent the defendant's omissions or misrepresentations, she would have purchased a cheaper alternative product. Id. at *13 (citations omitted). Although the plaintiff alleged she would have purchased an alternative cornstarch-based powder had she known of the increased cancer risk purportedly associated with baby powder, she did not allege that an alternative product would have been cheaper than baby powder. Id. at *14.

Finally, the Estrada court found that the plaintiff's premium price theory of economic harm did not sufficiently establish that she suffered an injury-in-fact. Estrada, 2017 WL 2999026, at *15. In premium price cases, a plaintiff alleges that the defendant's omissions or misrepresentations caused her to overpay for a product. Id. (citations omitted). Under that theory, the plaintiff claimed that as a result of Johnson & Johnson's omissions and misrepresentations, it was able to sell baby powder for more than it otherwise would have if consumers had been properly informed about the safety risks. The court determined that the plaintiff's "threadbare" allegation that she purchased baby powder at a premium, without any supporting factual allegations, was insufficient to establish an injury-in-fact. Id. It was significant in the court's analysis that the plaintiff did not allege that Johnson & Johnson advertised baby powder as superior to other products, nor did she identify any comparable, cheaper products to show that baby powder was sold at a premium price. Id.

2. The Amended Complaint Fails to Adequately Plead That Plaintiffs Suffered an Economic Injury-In-Fact.

In view of the foregoing authority, Plaintiffs here do not sufficiently allege that they suffered an economic injury to satisfy the injury-in-fact element of standing. At the outset, Plaintiffs allege that GNC sold supplements with false and misleading labeling and otherwise failed to disclose material facts about the dangers of ingesting picamilon, BMPEA and acacia rigidula. Am. Compl. ¶ 5. Plaintiffs then allege that they were hoodwinked into purchasing the supplements and would not have done so if GNC had disclosed that they contained mislabeled ingredients which supposedly pose serious health risks or were unlawful. Id. ¶¶ 6, 24. As a result of GNC's practices, Plaintiffs claim that they purchased supplements they otherwise would not have purchased, paid more for supplements than they otherwise would have paid⁷ and have been subjected to unreasonable safety risks. Id. ¶ 81. Based on these allegations, Plaintiffs apparently attempt

2017 WL 3971912

to assert two theories of economic injury: (1) they did not receive the benefit of their bargain; and (2) they paid a premium price for the supplements.⁸

⁷ In connection with Plaintiffs' various state law claims, Plaintiffs allege generally throughout the Amended Complaint that they purchased supplements from GNC that they otherwise would not have, or would not have paid as much for them as they did. See Am. Compl. ¶¶ 144, 154, 162, 172, 180, 213, 223, 232, 241, 259, 273, 279 and 282.

⁸ We note that the Amended Complaint contains no allegations that Plaintiffs would have purchased a cheaper, alternative product absent GNC's alleged omissions or misrepresentations, thus injury-in-fact cannot be established under an alternative product theory of economic injury. Further, to the extent that Plaintiffs urge that they have standing based upon concerns of health problems that have yet to occur, see Am. Compl. ¶ 81 (alleging that “[a]s a result of GNC's practices, Plaintiffs ... have been subjected to unreasonable safety risks”), apprehension concerning possible future injury is insufficient to establish injury-in-fact. Whitmore, 495 U.S. at 158; Reilly, 664 F.3d at 42.

*⁸ First, Plaintiffs' premium price allegations do not sufficiently establish that they suffered an economic injury. Although Plaintiffs broadly aver that GNC's alleged omissions and misrepresentations caused them to pay more for supplements than they otherwise would have paid, that “threadbare” allegation, without any supporting factual allegations, is insufficient to establish an injury-in-fact. See Estrada, 2017 WL 2999026, at *15 (“threadbare” allegation that the plaintiff purchased a product at a premium, without factual support, was insufficient to establish injury-in-fact); Young, 2012 WL 1372286, at *4 (finding no injury-in-fact where, *inter alia*, the plaintiff did not set forth allegations as to how he paid a premium price for the product). As in Estrada, the Court finds it significant that Plaintiffs do not allege GNC advertised the supplements they purchased as superior to other products, nor do Plaintiffs identify any comparable, cheaper products to show that the supplements they purchased from GNC were sold at a premium price. See Estrada, 2017 WL 2999026, at *15.

Next, Plaintiffs' allegation that they did not receive the benefit of their bargain when they purchased the supplements does not suffice to establish that they suffered an economic

injury-in-fact. As stated, Plaintiffs allege that they paid money for the supplements that, absent GNC's alleged omissions and misrepresentations, they otherwise would not have paid. See Am. Compl. ¶¶ 6, 24, 81; see supra n. 7. Although Plaintiffs do not allege that they consumed the supplements,⁹ they certainly do not claim they suffered any adverse health consequences from them. Furthermore, Plaintiffs do not allege that the supplements at issue, which are “primarily weight-loss and sports-nutrition supplements,” see Am. Compl. ¶ 27, failed to work for their intended purpose or did not deliver the advertised benefits.

⁹ Plaintiffs simply allege that they purchased the supplements on various occasions between 2011 and 2015. See Am. Compl. ¶¶ 11-22. However, in view of the fact that a number of Plaintiffs purchased supplements on multiple occasions over a period of months or years, see id. ¶¶ 11-13, 15, 17-21, it is logical to infer that they must have consumed the supplements. Indeed, it is highly unlikely that a consumer would make multiple purchases of items that he never used in the first place.

The Amended Complaint presents some of the same concerns as in Koronthaly, Young, James, Medley and Estrada, which ultimately led the courts to find that the plaintiffs in those cases did not suffer an injury-in-fact. As observed in Koronthaly and Young, Plaintiffs' purchases of the supplements were not made pursuant to a contract, thus they could not have been denied the benefit of any bargain. Beyond that, as in Koronthaly, Young, James, Medley and Estrada, Plaintiffs have not alleged that the supplements failed to work for their intended purpose of weight loss and/or sports nutrition, and there is no allegation that Plaintiffs' health was adversely affected.

While we accept as true Plaintiffs' allegation that they would not have purchased the supplements had they known the supplements purportedly contained dangerous ingredients, economic damages do not necessarily follow as a consequence. To the extent Plaintiffs consumed the supplements, see supra, n. 9, once they were used, there would be no economic injury for Plaintiffs to complain of and apprehension concerning future health consequences is insufficient to establish an injury-in-fact. See James, 2011 WL 198026, at *2; Medley, 2011 WL 159674, at *2. As in James and Medley, Plaintiffs would have received the benefit of their bargain so long as the supplements worked

as intended, meaning they provided weight-loss and sports nutrition benefits, and they produced no adverse health effects. See id. Nothing in the Amended Complaint suggests this was not the case.

Plaintiffs appear to base their benefit of the bargain theory upon GNC's alleged omissions and misrepresentations, claiming that GNC sold products with false and misleading labeling, and it otherwise failed to disclose material facts about the dangers of ingesting picamilon, BMPEA and acacia rigidula. See Am. Compl. ¶ 5. However, Plaintiffs do not allege what material facts GNC failed to disclose about the dangers of ingesting those substances or whether GNC had a duty to do so. Thus, the Court cannot conclude that Plaintiffs did not receive the benefit of their bargain based on alleged omissions by GNC. See Estrada, 2017 WL 2999026, at *6 (the plaintiff could not assert a benefit of the bargain theory of economic harm based on an omission where she failed to allege that the defendant was under a duty to disclose the omitted fact).

*9 In addition, the Court finds that Plaintiffs were not deprived of the benefit of their bargain based on alleged misrepresentations by GNC. As observed in Estrada, courts have found that a plaintiff did not receive the benefit of the bargain in cases where sufficient facts were pled for the court to conclude that the plaintiff was induced into purchasing the product at issue by a *specific* misrepresentation made by the defendant. See Estrada, 2017 WL 2999026, at *9–*11 (citations omitted). Unlike those cases, the plaintiff in Estrada did not sufficiently allege that she was induced into purchasing baby powder based on specific misrepresentations made by Johnson & Johnson on its website or on the product's label or advertisements. Id. at *11. Rather, the plaintiff simply alleged that she read the label prior to purchasing baby powder and in reliance on the label, she believed that baby powder was safe. Id. at *12.

Likewise, here, Plaintiffs fail to allege that they were induced into purchasing the supplements based on *specific* misrepresentations made by GNC. Plaintiffs allege that picamilon, BMPEA and acacia rigidula were “openly found” on the labels of various supplements available for sale at GNC; thus, through labeling, GNC misrepresented that the products were safe. See Am. Compl. ¶¶ 47, 65, 72, 79. Although Plaintiffs do not specifically allege it, they suggest that they read the labels on the supplements and believed they were safe. As in Estrada, that is insufficient, particularly in view of the fact that Plaintiffs do not otherwise allege they

were induced into purchasing the supplements by any specific statements on the labels.

In sum, the Court is well-aware that “[i]njury in fact is not Mount Everest,” Danvers Motor, 432 F.3d at 294, but, for the reasons explained herein, we conclude that Plaintiffs have not sufficiently alleged that they suffered an economic injury to satisfy the injury-in-fact element. Therefore, Plaintiffs have failed to establish that they have standing to bring the present action. Because Plaintiffs do not have standing, the Amended Complaint will be dismissed for lack of subject matter jurisdiction. Absent subject matter jurisdiction, the Court is without authority to rule on the remaining merit-based arguments.¹⁰ ACLU-NJ v. Township of Wall, 246 F.3d 258, 261 (3d Cir. 2001) (“If plaintiffs do not possess Article III standing, ... the District Court ... lack[s] subject matter jurisdiction to address the merits of plaintiffs' case.”).

¹⁰ Although the Court is not empowered to address GNC's arguments for dismissal under Rule 12(b)(6), and expresses no opinion on the merits of that motion, we note the possibility that GNC's preemption claim could be premature. “[F]ederal preemption is an affirmative defense on which the defendant bears the burden of proof.” In re Asbestos Prods. Liab. Litig., 822 F.3d 125, 133 n.6 (3d Cir. 2016). The Third Circuit has explained that “[t]his allocation of the burden of proof suggests that a motion under Rule 12(c) for judgment on the pleadings is a more appropriate procedural vehicle for dismissing cases on preemption grounds, instead of a motion under Rule 12(b)(6), except for cases in which preemption is manifest in the complaint itself.” Id. (citations omitted). As stated, the Court expresses no opinion at this juncture as to whether this is a case in which preemption is manifest in the complaint itself, but simply raises the issue for the parties' consideration at the appropriate time.

IV. CONCLUSION

Rule 15(a)(2) provides that leave to amend should be freely given “when justice so requires.” Fed.R.Civ.P. 15(a)(2). Therefore, to the extent that Plaintiffs wish to file a second amended complaint to cure the deficiencies discussed herein, they will be granted leave do so within 30 days from the date of this decision.

***10** Accordingly, the Motion to Dismiss filed by GNC as to Plaintiffs' lack of standing will be granted, and the Amended Complaint will be dismissed without prejudice at this time.

An appropriate order will be entered.

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TAB 25

 KeyCite Yellow Flag - Negative Treatment

Declined to Follow by [In re Smith & Nephew Birmingham Hip Resurfacing Hip Implant Products Liability Litigation](#), D.Md., August 5, 2019

2018 WL 4356638

Only the Westlaw citation is currently available.
United States District Court, D. Arizona.

IN RE: BARD IVC FILTERS
PRODUCTS LIABILITY LITIGATION,
Lisa Hyde and Mark E. Hyde,
a married couple, Plaintiffs,

v.

C. R. Bard, Inc., a New Jersey corporation;
and Bard Peripheral Vascular, Inc.,
an Arizona corporation, Defendants.

No. MDL 15-02641-PHX-DGC

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No. CV-16-00893-PHX-DGC

|

Signed September 11, 2018

|

Filed 09/12/2018

ORDER

David G. Campbell, Senior United States District Judge

*1 The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether jury trial on September 18, 2018. During the final pretrial conference held on September 6, 2018, it became clear that the parties disagree on whether Plaintiffs' negligence per se claim is impliedly preempted under [21 U.S.C. § 337\(a\)](#). The issue was raised and briefed by the parties in their proposed final pretrial order and jury instructions. Docs. 12388 at 8-12, 12438 at 54-61. The Court asked the parties during the pretrial conference whether they required further briefing and whether they wished to have this issue resolved before trial. Counsel for both sides stated that no further briefing was needed and that a ruling before trial would be helpful.

For the reasons stated below, the Court finds that the negligence per se claim is preempted. This conclusion is purely legal – it is not affected by the evidence that would be presented at trial. As a result, the Court concludes that it should enter judgment on this claim before trial under

Rule 56 of the Federal Rules of Civil Procedure. Although decisions under that rule normally are made in response to a formal motion for summary judgment, the rule makes clear that the Court may enter summary judgment *sua sponte*, provided the parties are notified of the Court's intention to make a dispositive decision and have an opportunity to respond. *See Fed. R. Civ. P. 56(f); see also Celotex Corp. v. Catrett, 477 U.S. 317, 326 (1986)* ("district courts are widely acknowledged to possess the power to enter summary judgments *sua sponte*, so long as the losing party was on notice that she had to come forward with all of her evidence"). In this instance, the question is purely one of law, the parties have been fully heard, and the parties seek a decision before trial. Such a decision will enable the parties to allocate their time and evidence to the issues to be considered by the jury.¹

¹ Another approach would be to treat this issue as a motion by Defendants for judgment as a matter of law under Rule 50. Although the standard for deciding such a motion is the same as the standard under **Rule 56**, the Ninth Circuit has held that a Rule 50 motion cannot be made before trial. *See McSherry v. City of Long Beach, 423 F.3d 1015, 1019-22 (9th Cir. 2005)*. The Court accordingly will enter judgment under **Rule 56**.

I. Background.

Plaintiff Lisa Hyde received a Bard IVC filter implant in 2011. In 2014, she learned that the filter had tilted, perforated the IVC wall, and fractured. The filter and [fractured limbs](#) were removed three months later.

Mrs. Hyde and her husband assert various claims. Doc. 364; Doc. 1, Case No. CV-16-00893. Applying Wisconsin law, the Court granted summary judgment to Defendants on several claims. Doc. 12007. Plaintiffs continue to assert claims for strict liability design defect (Count III), negligent design (Count IV), negligence per se (Count IX), loss of consortium (Count XV), and punitive damages. *Id.* at 19.²

² Defendants have explained that they did not seek summary judgment on the negligence per se claim because they did not know the basis for the claim until the parties prepared the proposed final pretrial order.

II. Discussion.

*2 Under Wisconsin law, negligence per se is a form of negligence that results from violation of a statute. See *Friederichs v. Huebner*, 329 N.W.2d 890, 917 (Wis. 1983). For the violation of a safety statute to constitute negligence per se, the plaintiff “must show: (1) the harm inflicted was the type the statute was designed to prevent; (2) the person injured was within the class of persons sought to be protected; and (3) there is some expression of legislative intent that the statute become a basis for the imposition of civil liability.” *Tatur v. Solsrud*, 498 N.W.2d 232, 235 (D. Wis. 1993) (citing *Walker v. Bignell*, 301 N.W.2d 447, 454 (Wis. 1981)).

Plaintiffs do not allege violation of a Wisconsin statute as part of their negligence per se claim. Rather, they contend that Defendants violated various provisions of the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, and related federal regulations, in designing the Bard filter. Docs. 12388 at 8-9 (final pretrial order), 12400 at 4-7 (trial brief), 12438 at 54-59 (proposed jury instructions). Specifically, Plaintiffs allege violations of 21 U.S.C. §§ 321, 331, and 352, and 21 C.F.R. §§ 803, 806.1, 820.100, 820.198, and 820.250. *Id.*; see Doc. 364 ¶ 231.

As noted above, the third element of Wisconsin’s negligence per se claim requires “some expression of legislative intent that the statute become a basis for the imposition of civil liability.” *Tatur*, 498 N.W.2d at 235. As other courts have recognized, however, “[f]ar from containing an expression that FDA regulations are intended to form the basis for civil liability, the [FDCA] expresses the opposite intention.” *Cali v. Danek Med., Inc.*, 24 F. Supp. 2d 941, 954 (W.D. Wis. 1998). Under § 337(a), “[v]iolations of the FDA are enforceable only by the United States.” *Id.* “The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Thus, “a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist.” *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011) (citation omitted); see *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) (noting that under § 337(a) “no private right of action exists for a violation of the FDCA”).

In *Buckman*, the Supreme Court held that a state law claim that a defendant made fraudulent statements to the FDA,

in violation of the FDCA, was impliedly preempted by § 337(a) because the claim “exist[ed] solely by virtue” of FDCA requirements and therefore “would not be relying on traditional state tort law which had predated the [FDCA].” 531 U.S. at 353. The same is true here. Plaintiffs’ “claim of negligence per se would not exist prior to the enactment of the FDCA ... because the claim only alleges violation of that law.” *Leonard*, 2011 WL 3652311, at *8. As in *Buckman*, Plaintiffs’ “negligence per se claim (or, more appropriately characterized, [their] negligence claim based solely on violations of ... FDA regulations) is impliedly preempted by the FDCA.” *Grant v. Corin Grp. PLC*, No. 3:15-CV-169-CAB-BLM, 2016 WL 4447523, at *4 (S.D. Cal. Jan. 15, 2016); see *Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-EJD, 2017 WL 3619612, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim preempted where it was “based entirely on violations of the FDCA and its implementing regulations”); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) (“If Plaintiffs claim negligence based solely on Defendants’ failure to comply with federal law or solely on illegal off-label promotion (i.e. negligence per se), Plaintiffs’ claims are impliedly preempted under *Buckman*.”); *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014) (“[A] negligence per se claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages. Since the latter is not available as a result of § 337(a), the Court finds that the former is preempted as well.”); *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013) (“Plaintiff’s attempt to recast a claim for violation of the FDCA as a state-law negligence claim is impliedly barred by § 337(a).”); *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) (“[T]o the extent that Plaintiff seeks to ground her negligence per se ... claim[] on allegations that Defendant violated the FDCA – namely, by selling a misbranded and adulterated product – these claims are impliedly preempted pursuant to 21 U.S.C. § 337(a).”); *Talley v. Danek Med., Inc.*, 7 F. Supp. 2d 725, 731 (E.D. Va. 1998) (“[T]he FDCA expressly prohibits the bringing of a private cause of action under the Act. To allow a state negligence per se action based upon alleged violations of the FDCA would defeat the purpose of that prohibition.”).

*3 Plaintiffs’ citation of *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809, 816 (E.D. Wis. 2015), is not persuasive. Doc. 12388 at 9-10. The plaintiff in that case did not bring a negligence per se claim, but instead asserted traditional common law torts such as design defect, failure to warn, and

negligence. *Garross*, 77 F. Supp. 3d at 813. Those claims were not impliedly preempted under *Buckman* “because none of them [arose] solely from a violation of federal law; rather, each [arose] from an independent, well-recognized duty owed under state law.” *Id.* at 816; *see also Hoffmann v. Wis. Elec. Power Co.*, 664 N.W.2d 55, 62 (Wis. 2003) (noting that “the enactment of safety statutes … does not abolish the duty arising under common-law negligence”). In this case, Plaintiffs retain and will assert at trial a common law negligent design claim; that claim is not affected by this ruling.

Plaintiffs cite cases holding that violations of FDCA regulations may support negligence per se claims in Wisconsin. Doc. 12388 at 9-10 (citing *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 964 (E.D. Wis. 1981) (pre-*Buckman* decision holding that violation of federal regulation for prescription drug labeling supported negligence per se claim under Wisconsin law); *Marvin v. Zydus Pharms. (USA) Inc.*, 203 F. Supp. 3d 985, 992 (W.D. Wis. 2016) (finding that plaintiffs may bring a negligence per se claim under Wisconsin law based on a violation of federal medication guide regulations); Doc. 12400 at 13 (citing *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 874 (Wis. Ct. App.

2004) (“In Wisconsin, violations of the FDA regulations may constitute negligence per se.”)). But these cases are squarely at odds with § 337(a). The plain language of that section and the *Buckman* decision indicate that such claims fail. *See Dunbar*, 2014 WL 3056026, at *6. Even if state law recognizes the claims, federal law preempts them. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (finding state law claim preempted where the plaintiff was not suing under state law for conduct that happens to violate the FDCA, but instead is suing solely “because the conduct violates the FDCA.”) (emphasis in original). This Court reached the same conclusion in previous bellwether cases. *See* Docs. 8874 at 14-18, 10404 at 14-17 (finding negligence per se claims impliedly preempted in the Booker and Jones bellwether cases).

IT IS ORDERED that judgment is entered in favor of Defendants on Plaintiffs' negligence per se claim (Count IX).

All Citations

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TAB 26

2009 WL 2433468

United States District Court, S.D. West Virginia.

In re DIGITEK PRODUCTS
LIABILITY LITIGATION.

This Order Relates to All Cases.

MDL No. 2:08-md-01968.

|

Aug. 3, 2009.

**PRETRIAL ORDER # 33 (Memorandum
Opinion and Order re Motions to Dismiss)**

JOSEPH R. GOODWIN, Chief Judge.

***1** Pending are the motions to dismiss filed by Mylan Inc., Mylan Pharmaceuticals Inc., Mylan Bertek Pharmaceuticals Inc., and UDL Laboratories, Inc. (“Mylan Defendants”) relating to Counts One, Two and Three of the Master Consolidated Complaint (“master complaint”) [Docket 100] and the motions to dismiss filed by all Defendants relating to Counts Five and Eighteen [Docket 102 and 105]. For the reasons that follow, I **DENY** the Mylan Defendants' motion to dismiss Count One and Defendants' motion to dismiss Count Five. I also **DENY WITHOUT PREJUDICE** the Mylan Defendants' motion to dismiss Counts Two and Three and Defendants' motion to dismiss Count Eighteen.

I.

Defendants Actavis Totowa, LLC (“Actavis Totowa”), Mylan Bertek Pharmaceuticals, Inc., and UDL Laboratories, Inc., are citizens respectively of New Jersey, Delaware, Texas, and Illinois. Defendants Actavis, Inc., and Actavis Elizabeth, Inc., are citizens of Delaware. Plaintiffs allege those defendants manufactured, marketed, tested, promoted, sold and/or distributed **Digitek®** (“**Digitek®**” or “**Digoxin**” interchangeably). Defendants Mylan, Inc., and Mylan Pharmaceuticals, Inc., are respectively citizens of Pennsylvania and West Virginia. Plaintiffs allege those defendants marketed, promoted, sold and/or distributed **Digoxin**. Mylan Pharmaceuticals, Inc., is also alleged to have distributed **Digitek® (Digoxin)** through its affiliates, Mylan Bertek Pharmaceuticals, Inc. and UDL Laboratories, Inc..

Digitek® is the brand-name of a cardiac glycoside, a compound affecting the myocardium of the heart. The drug is widely used to treat various heart conditions, including **atrial fibrillation**, **atrial flutter**, and **heart failure** that are uncontrolled by other medications. The United States Food and Drug Administration (“FDA”) approved the drug with a certain level of the active ingredient, in the following dosages: (1) **Digitek® (Digoxin tablets, USP)** 0.125mg, and (b) **Digitek® (Digoxin tablets, USP)** 0.250 mg. The approved quantities are important because **Digitek®** has a narrow therapeutic index. Specifically, there is a limited margin between effectiveness and toxicity. An excessive dose of the active ingredient can cause result in serious health problems and death.

The plaintiffs allege that some of the **Digitek®** at issue in this action was, among other things, designed and manufactured at a plant in Little Falls, New Jersey (“Little Falls facility”), owned by one or more of the defendants. On or about August 15, 2006, the FDA issued a letter warning to the defendants through Actavis Totowa, LLC, for failing to file periodic safety reports from the Little Falls facility (“August 2006 Warning Letter”). The FDA cautioned that the defendants, through Actavis Totowa, LLC, had violated federal adverse medical event reporting obligations, marketed drugs without proper clearance, and caused at least twenty-six (26) adverse drug experiences (“ADEs”) by failing to submit periodic safety reports. The August 2006 Warning Letter also noted an FDA inspection in early 2006 that revealed six potentially serious and unexpected adverse drug events dating back to 1999 for products, including **Digoxin**, that were not properly reported to the agency. The plaintiffs additionally allege that the defendants, through Actavis Totowa, LLC, were alerted that they were (1) not properly investigating serious and unexpected ADEs, (2) not adequately reviewing ADE information, (3) failing to develop proper procedures for surveillance, receipt, evaluation and reporting of ADEs, and (4) failing to file periodic safety reports which resulted in the twenty-six (26) unreported ADEs.

***2** On or about February 1, 2007, the FDA issued a Revised Warning Letter to the defendants through Actavis Totowa (“Revised Warning Letter”). It cited “significant deviations from the current Good Manufacturing Practice [‘cGMP’] regulations.” This likely accounts for the plaintiffs' allegation that the defendants' manufacturing, production, testing and inspection processes did not meet the then-current cGMP regulations found in 21 C.F.R. §§ 210 and 211. The cGMP regulations describe the methods, controls, equipment,

and facilities that must be in place for drug manufacturing operations. The regulations serve to ensure consumer safety and a drug's consistency with its purported identity, strength, quality, and purity.

The plaintiffs allege that the deviations resulted in the adulteration of drugs manufactured by the defendants, and were observed by the FDA, during inspections on July 10 and August 10, 2006. According to the FDA's Revised Warning Letter:

Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.

(Master Compl. ¶ 29).

On August 10, 2006, the deviations were presented to Actavis Totowa on an FDA-483 ("List of Inspections").

The Revised Warning Letter also cited deficiencies in the operations of the quality control unit, which included instances where the unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results for drug products. Specifically, according to the Revised Warning Letter:

Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting

without any justification for discarding the initial out-of-specification test results.

(Master Compl. ¶ 31).

The Revised Warning Letter also stated that analysts did not always document the preparation and testing of samples at the time they were performed:

Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples. Although your firm's procedures require the collection of in-process blend uniformity samples of three times the weight of finished product tablets or capsules, master production records do not require, and batch records do not contain, documentation that the samples are being collected accordingly.

(Master Compl. ¶ 32).

*3 The FDA also cited a failure to assure the accuracy of the input and outputs from a system used to run the **high-performance liquid chromatography** testing during drug analysis. Other deficiencies cited by the FDA in the Revised Warning Letter include: (1) a failure of the quality control unit to recognize that some tablets did not meet in-process specifications; (2) inconsistent documentation of failures to meet in-process specifications during tablet compression operations and failure to show that process deviations were promptly corrected to avoid releasing out of specification tablets; (3) a lack of adequate procedures for conducting bulk product holding time studies; (4) a failure to identify and control rejected in-process materials; (5) inadequate qualification of select equipment; and (5) a failure to establish and follow written procedures for maintaining manufacturing equipment.

An example found in the Revised Warning Letter provides as follows concerning Actavis Totowa's manufacturing processes:

Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)] For example: a) Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: ... **Digoxin** Tablets, USP, 0.25mg.

[W]e are concerned about the quality of drug products that have been released from your facility under the serious lack of cGMP controls found during the inspection. Your response provides no assurance that the records and conditions of manufacture and testing of each such lot of drug products released and marketed by your firm will be evaluated to assure that the released drug products have their appropriate identity, strength, quality and purity.

(Master Compl. ¶ 35).

As a result of the inspection findings, the defendants, through Actavis Totowa, were allotted 15 working days to provide a written listing of all unexpired, released lots of finished drug products associated with any out-of-specification test results during manufacture. Additionally, the FDA ordered a description of the actions taken to ensure that lots were suitable for release.

A Class I Recall of a drug is instituted only when "there is a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death." On or about April 25, 2008, the FDA announced a Class I Recall of all lots of Bertek and UDL Laboratories Digitek® (Digoxin) ("recalled Digitek® (**Digoxin**)"). The Class I recall stated as follows:

Digitek (Digoxin Tablets, USP): Audience: Cardiologists, family physicians, pharmacists, other healthcare professionals, patients [Posted 04/28/2008] Actavis Totowa LLC notified healthcare professionals of a Class I nationwide recall of all strengths of **Digitek**, a drug used to treat **heart failure** and abnormal heart rhythms.

*4 The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label—The product is being recalled due to the possibility that tablets with

double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of **digitalis toxicity** in patients with **renal failure**. **Digitalis toxicity** can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Several reports of illnesses and injuries have been reported. Patients should contact their healthcare professional with questions. [April 25, 2008—Press Release—Actavis Totowa, LLC]

(Master Compl. ¶ 38).

The plaintiffs allege that the Recalled **Digitek® (Digoxin)** is an adulterated drug. They also contend that its label and packaging are misbranded. The defendants are charged with having failed to inform the medical community and the public, including the plaintiffs, of the following material items:

1. How many and which lots of **Digitek® (Digoxin)** contained amounts of unapproved **Digoxin**;
2. How long the defendants manufactured and produced the recalled **Digitek®** ... and how long the adulterated drug was supplied, sold, distributed, and released into the stream of commerce;
3. How many reports of illness and injuries have been received; and
4. The nature and extent of the reports of illness and injuries that were received.

The plaintiffs allege that these failures are consistent with the safety violations which led the FDA to issue the August 2006 Warning Letter and their failure to satisfy the cGMP regulations, including:

1. Deviating, without written justification, from their own written specifications, test procedures, and laboratory mechanisms, 21 C.F.R. § 211.160(a);
2. Failing to establish the accuracy, specificity, and reproducibility of the test methods they employed, 21 C.F.R. § 211.165(d);
3. Maintaining incomplete laboratory records of all testing data, 21 C.F.R. § 211.194(a)(4);
4. Failing to verify the suitability of all testing methods used under actual conditions of use, 21 C.F.R. § 211.194(a)(2);

5. Failing to investigate unexplained out-of-specification testing results for drugs, 21 C.F.R. § 211.192;
6. Failing to follow the defendants' own written stability testing program, 21 C.F.R. § 211.166(a);
7. Failing to record and justify deviations from the defendants' own written production and process control procedures, 21 C.F.R. § 211.100(b) ¹²
8. Failing to examine and test samples to ensure that in-process materials conform to their specifications, 21 C.F.R. § 211.110(b);
9. Failing to follow defendant's own written quality control procedures, 21 C.F.R. § 211.22(d);
10. Failing to ensure that all data was reviewed and laboratory deviations were fully investigated and resolved prior to the release of drugs into commercial distribution, 21 C.F.R. § 211.22(a);
- *5 11. Failing to have laboratory controls sufficient to ensure that components, in-process materials, and finished drug products have the appropriate standards of identify, strength, quality, and purity and conform to their written specifications, 21 C.F.R. § 211.160(b); and
12. Failing to reject products that do not meet established standards or specifications and any other relevant quality control criteria, 21 C.F.R. § 211.165(f).

Noting the “serious manufacturing practice, quality assurance and product safety issues with the production of Digitek® ... as well as other products produced, manufactured, tested, marketed, distributed and sold or otherwise placed into the stream of commerce by Defendants[,]” the plaintiffs further allege that the Class—I recall for all-lots, all-doses of Digitek® bearing the defendants' labels resulted in the stoppage of production lines and the shutting of the Little Falls plant.

The plaintiffs charge that the defendants, during the events outlined above, have “repeatedly emphasized their reputations for quality manufacturing in publically available corporate documents and corporate run websites ... and under-reported, underestimated and/or downplayed the serious dangers and the defective nature of Digitek® ...” (Master Compl. ¶¶ 46–47). The plaintiffs further allege that the defendants “have a history of [(1)] releasing drug products for public consumption that have been adulterated or

misbranded ... [(2)] ... failing reliably to establish the identity, strength, quality and purity of drug products they release for public consumption ... [and (3)] failing adequately to investigate and document test results on their drug products. (*Id.* at 48–50).

The plaintiffs' factual allegations conclude with the following representations concerning the defendants' omissions:

The defendants are drug companies, that upon information and belief, engaged in the marketing, design, development, manufacture, production, processing, compounding, formulating, testing, sale, labeling, packaging, dosing, advertising, promotion, supplying, releasing and/or distribution of Digitek® ... tablets with amounts of the active ingredient that was not consistent among Digitek® ... tablets and amounts of the active ingredient that was inconsistent with the dose on the Digitek® ... label.... At all times relevant to this action, Defendants knew, and/or had reason to know that the recalled Digitek® ... tablets were not safe for the patients for whom the drug was prescribed because inconsistent or excess does of Digoxin can cause serious medical problems, **Digoxin overdose**, **Digitalis toxicity** and, in certain patients, catastrophic injuries and death.... Defendants failed to adequately warn users of the defective drug of its unreasonably dangerous characteristics due to the inconsistent and/or excess levels of active ingredient the drug contained.

*6 (*Id.* at 51–53).

The filing of various civil actions in state and federal courts across the country followed the recall, in which plaintiffs claimed injuries from alleged exposure to defectively manufactured Digitek®. On August 13, 2008, the Judicial Panel on Multidistrict Litigation entered an order establishing a multidistrict litigation (“MDL”) proceeding in this District

consolidating federal Digitek® related actions for joint case management. In Pre-trial Order # 10, dated January 29, 2009, the court directed the filing of a Master Complaint. The

Count One:	Failure to Warn and Instruct	Count Eleven:	Constructive Fraud
Count Two:	Manufacturing Defect	Count Twelve:	Violation of the WVCCPA
Count Three:	Design Defect	Count Thirteen:	Other UTPA Violations
Count Four:	Negligence	Count Fourteen:	Wrongful Death
Count Five:	Negligence per Se	Count Fifteen:	Survival Action
Count Six:	Breach of Implied Warranty	Count Sixteen:	Medical Monitoring
Count Seven:	Breach of Express Warranty	Count Seventeen:	Unjust Enrichment
Count Eight:	Negligent Misrepresentation	Count Eighteen:	Medicare MSP Liability
Count Nine:	Intentional Misrepresentation	Count Nineteen:	Loss of Consortium
Count Ten:	Fraud		

At the conclusion of Counts One, Two and Three, the plaintiffs allege that “[a]s a direct and proximate result of Defendants' acts and omissions, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.” (Master Compl. at ¶¶ 65, 73, and 81. Count Five alleges that “[a]s a direct and proximate result of Defendants' negligent, reckless, willful, wanton and grossly negligent acts and omissions” the same types of losses occurred. (*Id.* at 97). Count Eighteen, previously quoted in full, contains allegations of personal injury claims and “expenditures resulting from their injuries suffered in connection with the recalled Digitek (Digoxin).” (*Id.* at 175).

On April 20, 2009, the Mylan Defendants moved to dismiss Counts One, Two and Three, and all of the defendants moved to dismiss Counts Five and Eighteen. Responses were received on May 19, 2009 and replies on June 2, 2009.

II.

Master Complaint filed on February, 9, 2009, alleges the following claims:

Count One: Failure to Warn and Instruct

Count Two: Manufacturing Defect

Count Three: Design Defect

Count Four: Negligence

Count Five: Negligence per Se

Count Six: Breach of Implied Warranty

Count Seven: Breach of Express Warranty

Count Eight: Negligent Misrepresentation

Count Nine: Intentional Misrepresentation

Count Ten: Fraud

A. Governing Standard

Federal Rule of Civil Procedure 8(a)(2) requires that a pleader provide “a short and plain statement of the claim showing ... entitle[ment] to relief.” Fed.R.Civ.P. 8(a)(2); *Erickson v. Pardus*, 127 S.Ct. 2197, 2200 (2007). Rule 12(b)(6) correspondingly permits a defendant to challenge a complaint when it “fail[s] to state a claim upon which relief can be granted ...” Fed.R.Civ.P. 12(b)(6).

The required “short and plain statement” must provide “‘fair notice of what the ... claim is and the grounds upon which it rests.’” *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1964 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957), *overruled on other grounds*, *Twombly*, 127 S.Ct. at 1969); *see also Anderson v. Sara Lee Corp.*, 508 F.3d 181, 188 (4th Cir.2007). Additionally, the showing of an “entitlement to relief” amounts to “more than labels and conclusions....” *Twombly*, 127 S.Ct. at 1965. It is now settled that “a formulaic recitation of the elements of a cause of action will not do.” *Id.*; *Giarratano v. Johnson*, 521 F.3d 298, 304 (4th Cir.2008).

*7 The complaint need not, however, “make a case” against a defendant or even “forecast evidence sufficient to prove an element” of the claim. *Chao v. Rivendell Woods, Inc.*,

415 F.3d 342, 349 (4th Cir.2005) (quoting *Idice v. United States*, 289 F.3d 270, 281 (4th Cir.2002)). Instead, the opening pleading need only contain “[f]actual allegations ... [sufficient] to raise a right to relief above the speculative level.” *Twombly*, 127 S.Ct. at 1965; *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009) (noting the opening pleading “does not require ‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.”). Stated another way, the complaint must allege “enough facts to state a claim to relief that is plausible on its face.” *Id.* at 1974; *Giarratano*, 521 F.3d at 302. The recent decision in *Iqbal* provides some guidance concerning the plausibility requirement:

A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a “probability requirement,” but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are “merely consistent with” a defendant’s liability, it “stops short of the line between possibility and plausibility of ‘entitlement to relief.’”

Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.... Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not “show[n]”—“that the pleader is entitled to relief.”

In keeping with these principles a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

Iqbal, 129 S.Ct. at 1949–50 (citations omitted).

As noted in *Iqbal*, the Supreme Court has consistently interpreted the **Rule 12(b)(6)** standard to require a district

court to “ ‘accept as true all of the factual allegations contained in the complaint’ ” *Erickson*, 127 S.Ct. at 2200 (quoting *Twombly*, 127 S.Ct. at 1965); *see also South Carolina Dept. of Health And Environmental Control v. Commerce and Industry Ins. Co.*, 372 F.3d 245, 255 (4th Cir.2004) (quoting *Franks v. Ross*, 313 F.3d 184, 192 (4th Cir.2002)). The court is additionally required to “draw[] all reasonable ... inferences from those facts in the plaintiff’s favor” *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir.1999).

*8 As a further overlay to this deferential standard, MDL courts have observed generally that a “master complaint should not be given the same effect as an ordinary complaint. Instead, it should be considered as only an administrative device to aid efficiency and economy.” *See In re Propulsid Products Liability Litig.*, 208 F.R.D. 133, 142 (E.D.La.2002); *see also In re Vioxx Products Liability Litig.*, 239 F.R.D. 450, 454 (E.D.La.2006) (noting that a master complaint is simply “an administrative device used to aid efficiency and economy and, thus, should not be given the status of an ordinary complaint.”); *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 56 (D.N.J.2009) (“In the absence of ... consent, the majority of courts treat consolidated complaints filed in multi-district litigations as a procedural device rather than a substantive pleading with the power to alter the choice of law rules applicable to the plaintiffs’ claims.”); *Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 489 F.Supp.2d 932, 936 (D.C.Minn.2007) (“The transfer under [28 U.S.C.] § 1407, even after the filing of an amended complaint, is only a change in courtrooms. Consolidation of a master complaint is merely a procedural device designed to promote judicial economy, and, as such, it does not affect the rights of the parties in separate suits.”).

The administrative nature of a master complaint and its focus on facilitating management of the litigation, as opposed to being a primary operative pleading, has been considered in analyzing the motions to dismiss. Since it is uncertain how a master complaint should be treated when it is challenged via **Rule 12(b)(6)**, the document has been read and construed at this point in the litigation in light of its procedural purpose.

B. Count One—Failure to Warn

The Mylan defendants claim it has not been alleged that they, as distributors, knew or had reason to know of the existence of a manufacturing defect prior to the recall. The Mylan Defendants further contend that they cannot be held liable for a failure to warn because there are no instructions or warnings

that could have made Digitek® safe for consumers under the alleged circumstances.

The Mylan defendants are correct that the master complaint lacks detailed factual allegations respecting their specific knowledge of a manufacturing defect. It does allege though that all of the defendants knew generally of a manufacturing defect and that they failed to act. Paragraphs 51–53, quoted above, are illustrative. (See, e.g., ¶¶ 54–63).¹ The plaintiffs contend in the master complaint that, among other alleged misdeeds, (1) the Mylan defendants were involved in multiple cases of adverse drug events, (2) a number of these potentially serious and unexpected events were related to products including *Digoxin*, (3) *Digoxin* was the subject of multiple advisory letters from the FDA, foregoing an ultimate recall of *Digitek*®, which would have been directed, at least in part, to the Mylan defendants, and (4) the Mylan defendants failed to appropriately inform the medical community and the public, including the plaintiffs, of (a) how many and which lots of *Digitek*® contained amounts of unapproved *Digoxin*, (b) how long the recalled *Digitek*® was manufactured, produced, supplied, sold, distributed, and released into the stream of commerce, and (c) the number, nature and extent of the reports of illness and injuries that had been received.

¹ The Mylan Defendants rely upon *Bryson v. Gonzales*, 534 F.3d 1282 (10th Cir.2008), for the proposition that a generic allegation aimed at multiple defendants does not allege facts sufficient to give notice or establish a plausible right to recovery. The decision in *Bryson* involved a pleading by an inmate convicted of sexual assault who spent 19 years in jail until exonerated by DNA evidence. He sued a host of officials, including a police chemist, a district attorney, and a former police chief, alleging that they falsely procured his original conviction and then prevented him from obtaining access to the DNA evidence. Among other factors readily distinguishing *Bryson* from this action is the court of appeals' observation that follows:

“In § 1983 cases, defendants often include the government agency and a number of government actors sued in their individual

capacities. Therefore it is particularly important in such circumstances that the complaint make clear exactly who is alleged to have done what to whom, to provide each individual with fair notice as to the basis of the claims against him or her, as distinguished from collective allegations against the state.”

Id. at 1290 (citation and quoted authority omitted).

*9 In the Count One the plaintiffs further outline that (1) *Digitek*® was in an unsafe, defective and inherently dangerous condition which was unreasonably dangerous to its users; (2) the labeling, packaging and warnings were insufficient to alert consumers, including the plaintiffs, of the dangerous risks and reactions associated with the recalled *Digitek*®; (3) the plaintiffs are alleged to be in a class of persons that the defendants, including Mylan defendants, should have been considered to be subject to harm caused by *Digitek*®'s defective nature; (4) the defendants knew, or should have known, through quality control procedures, testing, adverse event reporting or otherwise that *Digitek*® was in a defective condition and the label, warnings, and dosage information provided with the recalled *Digitek*® were not accurate and (5) the defendants failed to provide adequate and timely warnings or instructions regarding *Digitek*®. (Master Compl. at ¶¶ 57–61). Also pled is the Mylan defendants' default on its continuing duty to warn the plaintiffs of the dangers associated with the recalled *Digitek*® and the assertion that if they had done so, the plaintiffs would not have used it. (*Id.* at 63–64).

In applying *Twombly's* plausibility standard, each of these factual allegations is treated as entirely accurate, however true or misguided a fact finder might ultimately find them to be. Plaintiffs allege and infer that as distributors of the drug which was, at least in part, the subject of the FDA warning letters and the eventual recall, it is plausible the Mylan Defendants knew or had reason to know of the alleged manufacturing defects, and then failed to appropriately warn and instruct the plaintiffs. Additionally, the Mylan Defendants concede that a party may be held liable for failure to warn even if it only has “constructive knowledge” of a product's defective nature.

(See, e.g., Memo. in Supp. of Mot. to Dis. Cts. One, Two, and Three at 3).

Accordingly, the Master Complaint provides the Mylan Defendants adequate notice of the claims pled against them and, accepting the associated factual allegations as true, a plausible claim for relief is alleged in Count One. I **DENY** the Mylan Defendants' motion to dismiss Count One.²

² The Mylan Defendants assert in the alternative that no instructions or warnings could have made Digitek® safe under the circumstances. They appear to contend that if it is impossible to cure a potential defect, such as double thickness tablets mistakenly created, which cannot be rendered reasonably safe for consumers through adequate warnings, that the Mylan defendants should be exonerated as a matter of law as to Count One. No case law is cited for the proposition and Defendants did not further address the argument in their reply. I do not deem this contention to warrant dismissal of Count One at this early stage. Discovery will better illuminate the timing and substance of the knowledge possessed by the Mylan defendants, and the adequacy of any warnings they should have offered in light of those considerations.

C. Counts Two and Three—Product Liability—Manufacturing and Design Defect

The Mylan defendants next assert that Counts Two and Three should be dismissed because distributors that did not participate in a product's design or manufacture cannot be held liable for defects that arose in the product at those two stages of the manufacturing process. Plaintiffs contend that the law is to the contrary in a majority of jurisdictions. Both parties rely upon case law not dealing with allegations of a defective prescription drug. The entirety of the briefing on the point spans just a few pages.

The *Restatement (Third) of Torts* speaks to the liability of manufacturer and distributor defendants involved in the production and sale of defective prescription drugs. Section 6(e) provides as follows:

***10** (e) A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:

(1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or

(2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.

Restatement (Third) of Torts: Prod. Liab. § 6 (1998). The commentary to section 6(e) provides as follows:

h. Liability of retail seller of prescription drugs and medical devices for defective designs and defects due to inadequate instructions or warnings. The rule governing most products imposes liability on wholesalers and retailers for selling a defectively designed product, or one without adequate instructions or warnings, even though they have exercised reasonable care in marketing the product. See § 1, Comment e, and § 2, Comment o. Courts have refused to apply this general rule to nonmanufacturing retail sellers of prescription drugs and medical devices and, instead, have adopted the rule stated in Subsection (e). That rule subjects retailers to liability only if the product contains a manufacturing defect or if the retailer fails to exercise reasonable care in connection with distribution of the drug or medical device. In so limiting the liability of intermediary parties, courts have held that they should be permitted to rely on the special expertise of manufacturers, prescribing and treating health-care providers, and governmental regulatory agencies. They have also emphasized the needs of medical patients to have ready access to prescription drugs at reasonable prices.

Restatement (Third) of Torts: Prod. Liab. § 6 (1998) (comment.).

The Restatement approach casts doubt on a non-manufacturing party's liability for design defects, at least where that down-the-line entity is not negligent. See 1 David G. Owen *et al.*, *Madden & Owen on Products Liability* § 5:12 (3d ed.2009) (noting section "6(e) provides that retail sellers are subject only to negligence liability for selling such products containing design or warnings defects."); see 3 J.D. Lee & Barry Lindahl, *Modern Tort Law: Liability and Litigation* § 27:45 (2d ed.2009). At the same time, the Restatement approach has not been uniformly accepted. See 5 Roxanne Barton *et al.*, *Litigating Tort Cases* § 60:23 (2009) ("Indeed, the Wisconsin court declined to adopt the new

Restatement, noting that the new provision had been the subject of controversy, and that it had even been referred to by various commentators as ‘a wish list from manufacturing America’ and a vehicle for tort reform.”).

The unsettled and apparently complex nature of the law of the fifty states aside, a different issue also precludes dismissal at this juncture. The Mylan defendants contend that “[p]laintiffs are aware that [the] Mylan Defendants did not participate in the design or manufacture of Digitek®.” (Defs.’ Memo. in Supp. at 6). At the same time, they candidly concede that the matter is “not always consistently pleaded....” *Id.* The exact relationship between the defendants, their knowledge of material events, the timing of their receipt of that knowledge, and the impact those fact intensive questions may have on the application of the unsettled, governing law all counsel in favor of allowing the challenged Counts to proceed to discovery.

*11 At the conclusion of that process, the parties may brief the matter anew at summary judgment, supported by a multi-state survey of the governing law. I can then best determine whether the matter is suitable for coordinated resolution. Accordingly, I **DENY** without prejudice the Mylan Defendants’ motion to dismiss Counts Two and Three.

D. Count Five—Negligence Per Se

Count Five alleges a claim for negligence *per se*. Plaintiffs cite the Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 301, along with unstated “related amendments, codes and federal regulations provided there under, and other applicable laws, statutes, and regulations” as the legislatively imposed standard of care supporting their negligence *per se* claim (Master Compl. ¶ 91). After alleging that they reside within the class of individuals that the FDCA and the other unnamed “statutes and regulations” are designed to protect, they further contend as follows

Defendants’ acts constitute an adulteration and misbranding as defined by the ... [FDCA] and the regulations promulgated there from and constitutes a breach of duty under the theory of negligence *per se*.

Defendants’ manufacturing, production, testing and inspection processes are not good manufacturing processes in violation of the ... [FDCA] and the regulations promulgated therefrom and constitutes a breach of duty under the theory of negligence *per se*.

The acts and omissions set forth above, demonstrate that Defendants failed to meet the standard of care set by the applicable statutes and regulations, which were intended for the benefit of individuals such as Plaintiffs making Defendants negligent *per se*.

(Master Compl. ¶¶ 92–95).

The defendants initially moved to dismiss Count Five as an improper private FDCA enforcement action. In their response, Plaintiffs concede a private right of action does not exist under the FDCA. They clarified, however, that Count Five was solely based in negligence, with the FDCA merely serving as one component of the violations of law in which they claim defendants engaged. In reply, the defendants persist in asserting the claim fails as a matter of law.

The analysis is controlled by *Talley v. Danek Medical, Inc.*, 179 F.3d 154 (4th Cir.1999). In *Talley*, plaintiff had a medical device implanted. She asserted that the device was used for a purpose not approved by the FDA. The district court dismissed the action at summary judgment. Plaintiff asserted on appeal that genuine issues of material fact remained over whether defendant “violated the ... [FDCA] and that a violation of the FDCA constitutes negligence *per se* in Virginia.” *Id.* The court of appeals, in an opinion authored by Judge Niemeyer, first discussed generally the nature of a negligence *per se* claim:

[I]n negligence *per se* cases, the courts “adopt as the standard of conduct of a reasonable man the requirements of a legislative enactment or an administrative regulation.”

*12 An example illustrates the doctrine’s application. If the statutory speed limit on a road is 35 m.p.h. and the defendant drives 40 m.p.h., causing him to collide with the plaintiff pedestrian and to injure her, the plaintiff may establish the breach element of her negligence claim by pointing to the violation of the speed limit. The defendant is barred from putting on evidence, specific to his situation, that driving at 40 mph. on that particular road was reasonable because the “violation of the statute constitutes conclusive evidence of negligence.”

Id. at 158.

The decision in *Talley* also observes that the negligence *per se* doctrine “is not a magic transforming formula that automatically creates a private right of action for the civil enforcement, in tort law, of every statute.” *Id.* Instead, the

claim substitutes a standard of care created by the legislature for one that would otherwise be created by the common law. There are also limits placed on the doctrine to assure that it does not become a means to practically create private rights of action for statutory violations. The decision in *Talley* recognizes at least two means for “cabin[ing]” the doctrine:

First, not all statutory provisions dictate a standard of care, and therefore not all statutory violations can provide a basis for establishing negligence *per se*. Second, even when a statutory provision does specify a standard of care, a plaintiff must still prove the additional elements of duty, proximate causation, and injury to establish liability.

Id. at 159. A statute will be deemed not to define a standard of care where it only imposes an administrative requirement, “such as the [mandate] to obtain a license or to file a report to support a regulatory scheme....” *Id.*

The plaintiff in *Talley* asserted a violation of 21 U.S.C. § 360e(a), which requires premarket approval for certain medical devices.³ As noted, she asserted that premarket approval had not occurred because the implanted device was used in a manner not approved by the FDA. The court of appeals explained why her theory could not support a negligence *per se* claim:

³ Coincidentally, the plaintiff, as in this case, relied as well upon 21 U.S.C. § 331(a), which provides as follows:

The following acts and the causing thereof are prohibited:
(a) The introduction or delivery for introduction into interstate commerce of any ... drug ... that is adulterated or misbranded. *Id.* The court of appeals does not appear to have separately discussed the suitability of this subsection to support a negligence *per se* claim.

Breach of the requirement not to misbrand a surgical nail[, as in the case of *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455 (4th Cir.1960),] is similar to a breach of a speed

limit; each violates a specific and substantive standard of care that is intended to protect others. The holding in *Eutsler*, however, does not establish the principle that the simple failure to obtain approval of a device from the FDA, standing alone, can support a negligence *per se* claim. The administrative requirement that a given device be approved by the FDA before being marketed—as opposed to a specific substantive requirement that a device be safe and effective—is only a tool to facilitate administration of the underlying regulatory scheme. Because it lacks any independent substantive content, it does not impose a standard of care, the breach of which could form the basis of a negligence *per se* claim. Its breach is analogous to the failure to have a drivers license.

*13 *Id.* at 161.

Unlike the mandate of section 360e(a), and the circumstances in *Talley*, Count Five, and section 331(a), speak to the breach of a clear cut statutory prohibition. Specifically, Congress has commanded drug manufacturers not to deliver in interstate commerce any misbranded drug. Plaintiffs have, in addition to other violations, specifically alleged misbranding. The statutory directive found in section 331(a) is not unlike the unadorned legislative prohibition on exceeding a certain speed on an interstate highway. The analogy is, in light of the analysis in *Talley*, fatal to defendants' Rule 12(b)(6) challenge to Count Five. Accordingly, I DENY the defendants' motion to dismiss Count Five.

E. Count Eighteen—Medicare Secondary Payer Act

The defendants assert that Count Eighteen fails to state a claim because (1) it lacks an allegation that plaintiffs are a “primary plan[,]” and (2) defendants have no responsibility for any Medicare payments to the plaintiffs. Aside from an additional paragraph incorporating prior allegations, the entirety of Count Eighteen reads as follows:

In addition to their own personal injury claims, Plaintiffs, whose medical care costs arising from Digitek® (Digoxin) were paid in whole or in part by Medicare, bring this cause of action pursuant to the private cause of action provisions of the Medicare as Secondary Payer Statute [(“MSP”) 42 U.S.C. § 1395y(b)(3)(A)] to recover “double damages” of all Medicare expenditures resulting from

their injuries suffered in connection with the recalled **Digitek® (Digoxin)**.

(Master Compl. ¶ 175).

The United States Court of Appeals for the First Circuit recently explained the nature and workings of the MSP:

Prior to 1980, Medicare generally paid for medical services whether or not the Medicare beneficiary also was covered by another health plan. The MSP statute, which was enacted in 1980 to reduce federal health care costs, makes Medicare the secondary payer for medical services provided to Medicare beneficiaries whenever payment is available from another primary payer.

To that end, the MSP statute prohibits Medicare from making any payment to a beneficiary for medical expenses if “payment has been made, or can reasonably be expected to be made promptly (as determined in accordance with regulations) under ... an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance.” Should Medicare determine that the primary insurer has not paid and that no prompt payment reasonably can be expected from the primary insurer, however, Medicare may pay the beneficiary up front, but such payment is conditioned on Medicare’s right to reimbursement in the event that a primary plan later pays or is found responsible for payment of the item or service.

To facilitate recovery of these conditional payments, the MSP ... creates a private cause of action with double recovery to encourage private parties to bring actions to enforce Medicare’s rights....

*14 *United Seniors Ass'n, Inc. v. Philip Morris USA*, 500 F.3d 19, 21–22 (1st Cir.2007).

The Defendants primarily assert that their responsibility for any Medicare monies expended to treat plaintiffs must be judicially fixed before the MSP private right of action ripens, meaning Count Eighteen is premature. Plaintiffs assert that they are entitled to establish defendants liability under the MSP in the same action that would serve as the predicate to MSP liability. In the alternative, plaintiffs ask the court to bifurcate Count Eighteen until such time, if ever, that defendants' liability for plaintiffs' injuries is established.

To the extent it is not unanimous, the overwhelming weight of the case law has adopted the defendants' position. The United States Court of Appeals for the Eleventh Circuit recently observed as follows:

Our conclusion that **section 1395y(b)(3)** does not create a private cause of action against alleged—as opposed to proved—tortfeasors whose responsibility for payment of medical costs has not been previously established is supported by three additional considerations. First, Plaintiffs' proposed interpretation of **section 1395y(b)(3)(A)** would drastically expand federal court jurisdiction by creating a federal forum to litigate any state tort claim in which a business entity allegedly injured a Medicare beneficiary, without regard to diversity of citizenship or amount in controversy. Second, under Plaintiffs' interpretation, an alleged tortfeasor that is sued under the MSP (instead of under state tort law) could not contest liability without risking the penalty of double damages: defendants would have no opportunity to reimburse Medicare after responsibility was established but before the penalty attached. Third, Plaintiffs' proposed interpretation would allow individuals acting as private attorney generals to litigate the state tort liability of a defendant towards thousands of Medicare beneficiaries—as a predicate to showing MSP liability—without complying with class action requirements. We are confident that, if Congress intended such radical innovations in jurisdiction, federal-state relations, and tort liability, it would have more clearly expressed its intent.

Glover v. Liggett Group, Inc., 459 F.3d 1304, 1309 (11th Cir.2006); see also, e.g., *Mason v. American Tobacco Co.*,

346 F.3d 36, 43 (2nd Cir.2003)(observing that “[D]efendants are clearly correct when they assert that ‘the trigger for bringing a MSP claim is not the pendency of a disputed tort claim, but the established obligation to pay medical costs pursuant to a pre-existing arrangement to provide insurance benefits.’ ”); *National Committee to Preserve Social Sec. and Medicare v. Philip Morris USA Inc.*, 601 F.Supp.2d 505, 509 (E.D.N.Y.2009) (“Little discussion is required, as the weight of authority is entirely with defendants. Indeed, each of the federal courts to have considered the questions raised here has rejected plaintiffs’ view of the ... [MSP].”).

*15 The precise issue raised by the defendants has, however, recently been presented for decision to the United States Court of Appeals for the Fourth Circuit in *Bio-Medical Applications of N.C., Inc. v. Brooks Food Group, Inc.*, No. 08-1819 (4th Cir. Jul. 29, 2008). Oral argument is scheduled for September 22, 2009. Pending the decision in Brooks Food Group, **I DENY WITHOUT PREJUDICE** defendants’ motion to dismiss Count Eighteen.

III.

Based upon the foregoing analysis, I(1) **DENY** the Mylan Defendants’ motion to dismiss Count One and Defendants’

motion to dismiss Count Five, and (2) **DENY WITHOUT PREJUDICE** the Mylan Defendants’ motion to dismiss Counts Two and Three and Defendants’ motion to dismiss Count Eighteen.

The court **DIRECTS** the Clerk to file a copy of this memorandum opinion and order in 2:08-md-1968 which shall apply to each member Digitek-related case previously transferred to, removed to, or filed in this district, which includes counsel in all members cases up to and including civil action number 2-09-cv-875. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court’s website at www.wvsd.uscourts.gov.

All Citations

Not Reported in F.Supp.2d, 2009 WL 2433468, 74 Fed.R.Serv.3d 116

TAB 27

 KeyCite Yellow Flag - Negative Treatment
Distinguished by [Halperin v. Merck, Sharpe & Dohme Corp.](#), N.D.Ill., April 10, 2012

2011 WL 5903623

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION
United States District Court, D. New Jersey.

In re FOSAMAX (ALENDRONATE SODIUM)
PRODUCTS LIABILITY LITIGATION (NO. II).
Relates to All Actions.

MDL No. 2243.

|
Civ. No. 08-008 (GEB-LHG).

|
Nov. 21, 2011.

MEMORANDUM OPINION

BROWN, Chief Judge.

*1 This matter comes before the Court upon Defendants' Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals, LLC, Barr Laboratories, Inc., Mylan, Inc., Mylan Pharmaceuticals, Inc., and Apotex Corporation (collectively the "Generic Defendants"), and Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharmaceuticals Inc. on behalf of and formerly known as Cobalt Pharmaceuticals Company and Sun Pharmaceuticals (collectively "Watson Defendants") Motion for Judgment on the Pleadings. (Doc. No. 251.) Plaintiffs oppose the motion. (Doc. No. 296.) The Court has considered the parties' submissions and decided the matter without oral argument pursuant to [Federal Rule of Civil Procedure 78](#). For the reasons set forth on the record during the Court's November 14, 2011 conference and as set forth below, the Court grants in part and denies in part the motion.

I. BACKGROUND

The following facts are taken as true for purposes of deciding the instant motion. Plaintiffs in this case were prescribed **Fosamax** and its generic equivalent **alendronate** sodium, an oral medication for the treatment of **osteoporosis** and **Paget's disease**. The United States Food and Drug Administration ("FDA") approved Merck & Co. Inc.'s ("Merck") new drug application ("NDA") for **Fosamax** in September 1995. (Murphy Compl. ¶ 32.) Teva Pharmaceuticals developed the

generic form **alendronate** sodium, and FDA approved its abbreviated new drug application ("ANDA") on February 6, 2008. (*Id.* at ¶ 33.) In the following years, each of the Generic Defendants received approval for and/or marketed **alendronate** sodium.¹

¹ Plaintiffs allege that Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are not generic manufacturers. Watson counters that it has only sold generic Fosamax and asks the Court to take judicial notice of the "Approved Drug Products with Therapeutic Equivalence Evaluations," listing Watson as a generic manufacturer. However, as the Court stated during its November 14, 2011 ruling, the Court must take Plaintiffs' allegations as true. It would be inappropriate under the standard of [Fed.R.Civ.P. 12\(c\)](#) to make a factual determination otherwise. Consequently, the Court's reasoning and conclusions in this opinion as to the Generic Defendants are exclusive of the Watson Defendants.

Alendronate sodium is in a class of drugs known as bisphosphonates, which are indicated for several conditions including the treatment and prevention of **osteoporosis** in **post-menopausal** woman, treatment of increased bone mass in men, treatment of glucocorticoid-induced **osteoporosis** in men and women, and treatment of **Paget's disease** in men and women. (*Id.* at ¶¶ 35–36.) In patients with **osteoporosis**, the loss of live bone tissue causes the bones to become brittle, fragile, and therefore susceptible to fracture. (*Id.* at ¶ 37.) **Osteoporosis** can occur due to a decrease in vitamin D and estrogen, a reason why post-menopausal women are at an increased risk to develop the condition. (*Id.*)

With respect to estrogen-deprived patients specifically, there may be an increase in the number of osteoclasts, which are a type of bone cell that remove the mineralized matrix of the bone. (*Id.* at ¶ 38.) In healthy patients, another type of bone cell called an osteoblast balances osteoclast activity by building up bone tissue. (*Id.*) **Alendronate** sodium binds tightly to bone tissue, working to decrease the number of osteoclasts and thereby lessen bone breakdown. Consequently, the drug also increases bone mineralization. (*Id.* at ¶ 41.)

Plaintiffs claim that the result of decreased osteoclast activity is a compromised blood supply to the affected area, causing bone death or "**osteonecrosis**." (*Id.* at ¶ 45.) There are

two frequent locations in which Plaintiffs maintain that **osteonecrosis** may develop. (*Id.* at ¶ 47.) The first is the jaw. (*Id.* at ¶ 45.) A minor injury or disease in the jaw may turn into a non-healing **wound** because the bones making up the jaw are unable to mend properly. (*Id.* ¶ at 51.) FDA has received numerous reports of **osteonecrosis of the jaw** among users of **alendronate** sodium and recommended in January 2005 that Merck amend the labeling for **Fosamax** to warn of this risk. (*Id.* at ¶¶ 56, 58–60.) In July of 2005, Merck changed the **Fosamax** “precautions” section of the label to include reference to the reports of **osteonecrosis of the jaw** associated with a number of activities, including taking **Fosamax**. (*Id.* at ¶¶ 60, 62.) Plaintiffs point out that the “warning” section of the **Fosamax** label was not changed and they charge Merck with failing to affirmatively warn patients of the increased risk of **osteonecrosis of the jaw** associated with **Fosamax** use.² (*Id.* at ¶ 61.)

² The harm associated with **osteonecrosis** of the jaw in patients who were prescribed **Fosamax** is currently the subject of another MDL in U.S. District Court for the Southern District of New York—*Boles v. Merck & Co.*, Case No. 06–9455.

*² The second location for **osteonecrosis** is in the femur. (*Id.* at ¶ 69.) Three studies published in 2005, 2009, and early 2010 found and expressed concern regarding non-spinal fractures, including in the subtrochanteric area of the femur (just below the hip), in patients on long-term **alendronate** therapy. (*Id.* at ¶¶ 70,–72.) FDA issued a Safety Announcement on March 10, 2010 concerning potential adverse side effects associated with **Fosamax**. (*Id.* at ¶ 73.) But FDA concluded in this announcement that it did not believe there was enough data to support a clear causal link between bisphosphonates use and femur fractures. (*Id.* at ¶ 75.) It did, however, state that it was working with the American Society of Bone and Mineral Research Subtrochanteric **Femoral Fracture** Task Force to gather information on the issue. (*Id.* at ¶ 76.) The Task Force issued its report in September 2010, finding evidence of a relationship between long-term bisphosphonate use and **femoral fractures**. (*Id.* at ¶ 77.) But the report stopped short of concluding that there was a causal association. (*Id.*)

Nonetheless, FDA issued another Safety Announcement on October 13, 2010 with regard to bisphosphonates, including **Fosamax**. (*Id.* at ¶ 78.) FDA announced that information about the risk of fractures in patients who take bisphosphonates for **osteoporosis** would be included in the “indications and usage” section of the labeling and in Medication Guides. (*Id.*)

at ¶ 79.) The most-recent **Fosamax** label “warning” section, amended on January 25, 2011, contains no information about the risk, but the “precautions” section reports that “[a]typical, low-energy, or low trauma fractures of the femoral shaft have been reported in bisphosphonates-treated patients,” but that “[c]ausality has not been established.” (*Id.* at ¶¶ 80–83.)

On February 23, 2011, less than two months after Merck updated the **Fosamax** label, the Journal of the American Medical Association published a study, finding that, among older women, bisphosphonate treatment for longer than 5 years was associated with an increased risk of subtrochanteric or femoral shaft fractures. (*Id.* at ¶ 85.)

Plaintiffs allege injuries caused from the use of **alendronate** sodium.³ Plaintiffs claim that as a result of Generic Defendants' claims regarding the safety and efficacy of **alendronate** sodium, they were prescribed and used the drug long-term. Each alleges that as a direct and proximate cause of using **alendronate** sodium, they suffered fractures of the femur (sometimes both femurs), requiring hospitalization, surgery, and/or rehabilitation. As a result, the Plaintiffs claim significant harm; physical injury; enduring pain and suffering; bodily impairment; an increased risk of future **osteonecrosis of the jaw** and femur; risk of future hospitalizations, surgeries, and rehabilitation; mental anguish; emotional distress; and economic losses. Had Plaintiffs or their health-care-providers been made aware of unreasonable risks that Generic Defendants knew or should have known about, they would have not used or have been prescribed **alendronate** sodium.

³ Claims against Merck, Sharp & Dohme, Corp. arising out of the ingestion of branded-drug, **Fosamax**, are not at issue in this motion and not affected by the Court's conclusions.

*³ Accordingly, Plaintiffs brought suit in a variety of courts and venues. Merck moved for centralization of the actions, and on May 25, 2011, the United States Judicial Panel on Multidistrict Litigation ordered that outside actions and actions in the District of New Jersey be transferred here for coordinated and consolidated pretrial proceedings. (See Doc. No. 30.) Plaintiffs brought numerous causes of action arising under state law, which the Court categorizes into the following legal claims against the Generic Defendants:

- Defective Manufacturing;
- Defective Design;

- Failure to Warn;
- Negligence;
- Fraud, Misrepresentation, Failure to Conform to Representation;
- Negligent Misrepresentation;
- Breach of Express Warranty;
- Breach of Implied Warranty;
- Violation of Consumer Protection Laws;
- Restitution; and
- Loss of Consortium.

Generic Defendants now move for Judgment on the Pleadings under [Federal Rule of Civil Procedure 12\(c\)](#) on the basis that all of Plaintiffs' claims against them are preempted by federal law.

II. DISCUSSION

A. Standard of Review

A motion for judgment on the pleadings under [Federal Rule of Civil Procedure 12\(c\)](#) is governed by the same standard as a motion to dismiss under [Federal Rule of Civil Procedure 12\(b\)\(6\)](#). *Turbe v. Virgin Islands*, 938 F.2d 427, 428 (3d Cir.1991). A motion to dismiss under 12(b)(6) may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court finds that the plaintiff has failed to set forth fair notice of what the claim is and the grounds upon which it rests. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (citing *Conley v. Gibson*, 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)).

A complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. at 570). The plausibility standard requires that "the plaintiff plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged" and demands "more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). Although a court must accept as true all factual allegations in a complaint, that tenet is "inapplicable to legal conclusions," and "[a] pleading that

offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' " *Id.* (citing *Twombly*, 550 U.S. at 555); see also *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir.2008). In evaluating a motion to dismiss, a court may consider only the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the complainant's claims are based upon those documents. See *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir.1993).

B. Law of Preemption

*4 The Supremacy Clause states that federal law "shall be the supreme Law of the Land ... and any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." [U.S. Const. art. VI, cl. 2](#). Implied preemption, the type of preemption at issue in this motion, occurs when it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287, 115 S.Ct. 1483, 131 L.Ed.2d 385 (1995). In other words, when state law requires what federal law forbids, state law must give way. See *Wyeth v. Levine*, 555 U.S. 555, 583, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009).

In *PLIVA v. Mensing*, — U.S. —, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011) ("Mensing"), plaintiffs brought state failure-to-warn claims against several generic manufacturers of the drug [metoclopramide](#). *Mensing*, 131 S.Ct. at 2573. Plaintiffs contended that the generic manufacturers failed to change [metoclopramide](#) labeling to adequately warn of the risk of a severe [neurological disorder](#) called tardive dyskinesia, in violation of state tort law. *Id.* The state tort laws applicable in the case required manufacturers that are "or should be aware of [their] product's danger to label that product in a way that renders it reasonably safe." *Id.* at 2573. Consequently, the parties in *Mensing* agreed that manufacturers may be under a duty to change labeling to warn of dangers in order to comply with state law. *Id.*

On the other hand, under the Federal Food, Drug, and Cosmetic Act ("FDCA")⁴, the Court found that generic manufacturers have a federal duty of "sameness" to, at all times, insure that the label for the generic drug is identical to the label adorning the corresponding reference-listed drug. *Id.* at 2575. The plaintiffs insisted that there were several ways the generic manufacturers could have provided [metoclopramide](#) warnings to patients and prescribing physicians. First, plaintiffs argued that FDA's

“changes-being-effected” (CBE) process allowed generics manufacturers to add or strengthen warnings or precautions. *Id.* The Court, however, disagreed, concluding that the generic manufacturers may use the CBE process only to update their label to match the reference-listed drug's labeling. *Id.* In fact, had a generic manufacturer unilaterally changed its label through the CBE process, it would have been in violation of its duty of sameness. *Id.*

4 Because “all relevant events” in *Mensing* predated the Food and Drug Administration Amendments Act (FDAAA), the Court stated that “it expressed no view on the impact of the 2007 Act.” *Mensing*, 131 S.Ct. at 2574. Because events giving rise to the alleged injuries in this case occurred before and after 2007, this opinion will determine whether the FDAAA has any effect on the preemption analysis.

Second, the plaintiffs argued that the generic *metoclopramide* manufacturers should have sent “dear health care professional” (also known as “dear doctor”) letters to inform prescribing physicians of new or additional warnings. But again, the Court found this avenue unavailable to generics manufacturers because dear doctor letters are considered by the FDA to be “labeling” and must be “consistent with and not contrary to [the drug's] labeling.” *Id.* at 2576; *see also* 21 C.F.R. 201.100(d)(1). Therefore, if a generics manufacturer were to send a dear doctor letter containing new or additional warning information, it would violate the duty of sameness and misleadingly suggest a difference between the generic and corresponding branded drug. *Mensing*, 131 S.Ct. at 2576.

*5 Third, the plaintiffs maintained that the generic manufacturers could have proposed stronger labels to the FDA. If FDA agreed, the agency “would have worked with the brand-name manufacturer to create a new label for both the brand-name and the generic drug.” *Id.* The Court, however, concluded that even if a generic manufacturer has a duty to ask the FDA for assistance in changing the label, the request would not satisfy the state law duty. *Id.* at 2578. While the generic manufacturer “might eventually have been able to accomplish under federal law what state law requires,” it could not independently do so. *Id.*

Accordingly, the Court held “that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.” *Id.* at 2581. As a result, the *Mensing* plaintiffs' state failure-to-warn

claims were preempted “because it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.” *Id.* at 2587.

In this case, the Generic Defendants move for judgment on the pleadings arguing that federal drug regulations preempt all of Plaintiffs' state law claims. Specifically, they contend that the Supreme Court's decision in *Mensing* requires that all state law claims arising from allegedly defective alendronate sodium labeling be dismissed because it is impossible to comply with both federal drug regulations and state tort and statutory duties. Defendants insist that failure to adequately warn is at the heart of each of Plaintiffs' claims, and thus, Defendants conclude that all must be dismissed. The Court will analyze each of Plaintiffs' claims in turn.

C. Application

1. Defective Manufacturing

The defective manufacturing claims must be dismissed. Plaintiffs merely recite the elements for this claim stating that the alendronate sodium “placed in the stream of commerce by Defendants was defective in its manufacture and construction ... in that it deviated from product specification such that it was unreasonably dangerous to an ordinary user or consumer....” (Brown Compl. at ¶ 115; Murphy Compl. at ¶ 111.) But Plaintiffs provide no sort of factual allegations supporting this cause of action. In fact, the complaints are dedicated to alleging that alendronate sodium labeling and formulation (i.e., the design), not the manufacturing, are defective and dangerous. Therefore, Plaintiffs have provided no “more than a sheer possibility” that Generic Defendants defectively manufactured alendronate sodium. *Iqbal*, 129 S.Ct. at 1949. And this “formulaic recitation of the elements of a cause of action will not do.” *Id.* (citing *Twombly*, 550 U.S. at 555). Consequently, the Court need not even reach the question of preemption to conclude that Plaintiffs' defective manufacturing claims must be dismissed.

2. Defective Design

*6 Plaintiffs' claims alleging defective design are preempted. The Supreme Court found that that a generic drug is “designed to be a copy of a reference listed drug” and must be “identical in active ingredients, safety, and efficacy.” *Mensing*, 131 S.Ct. at 2574 n. 2; *see also* 21 U.S.C. § 355(j) (2)(A) (requirements for an ANDA). To gain admittance to the market, a generic must demonstrate pharmaceutical

equivalence and bioequivalence. *Id.* at § 355(j)(2)(A)(i)-(iii). Important here, an ANDA must also demonstrate that the “active ingredient of the new drug is the same as that of the listed drug.” *Id.* § 355(j)(2)(A)(ii)(I). Hence, the “duty of sameness” also applies in the context of generic drug design. *Mensing* stands for the principle that a federal duty of sameness arising out of FDA’s regulatory requirements preempts any conflicting tort duty arising under state law. *Mensing*, 131 S.Ct. at 2577–78.

Here, plaintiffs allege that Generic Defendants’ alendronate sodium should have been designed differently to comply with state tort law. Plaintiffs allege that bisphosphonates are a class of drug, of which alendronate sodium is a member, that have a demonstrated link to bone fractures. (Murphy Compl. at ¶85.) Thus, generic Fosamax was defectively designed because its active ingredient was “unreasonably dangerous,” “defective,” and that there “was both technical and economic feasibility ... of using an alternative design or formulation.” (*Id.* at ¶¶ 116, 124.) But “[i]t was not lawful under federal law for the Manufacturers to do what state law required of them,” *Mensing* 131 S.Ct. at 2577, because FDA requires generic Fosamax to have the same active ingredient as Fosamax (alendronate sodium). Therefore, Plaintiffs’ design claims are preempted.

3. Failure to Warn

Plaintiffs’ claims of failure to warn are squarely preempted by *Mensing*. The essence of Plaintiffs’ claim is that the alendronate sodium labeling was insufficient and that Generic Defendants failed to satisfy their state law duty to provide accurate warning of the risks of osteonecrosis associated with long-term use. (See, e.g., Murphy Compl. ¶¶ 81, 87, 101, 132; Brown Compl. ¶¶ 129, 130). Necessarily, under Plaintiffs’ theory, the Generic Defendants should have altered the alendronate sodium label to provide new, different, and stronger warnings. According to Plaintiffs, the Generic Defendants had knowledge of the dangerous side effects that could result from long-term alendronate sodium use but gave no warning of these side effects, all while concealing their knowledge of them. (Brown Compl. at ¶ 89, 93.)

But if the Generic Defendants “had independently changed their labels to satisfy their state-law duty, they would have violated federal law.” *Mensing*, 131 S.Ct. at 2578. Federal drug regulations “demand that generic drug labels be the same at all times as the corresponding brand-name drug labels.” *Id.* The Generic Defendants could not alter the labeling without action by the FDA or manufacturer of the

corresponding reference-listed drug.⁵ See *id.* at 2575–76. Plaintiffs’ insistence that Generic Defendants could have brought safety information to Merck misses the point. (See Pl.’s Opp Br. At 16; Doc. No. 296.) Even if Generic Defendants had bypassed the FDA and taken their safety information to Merck directly, they would still be unable to change alendronate sodium labeling themselves. Alteration of the generic label ultimately depends on the actions of a third party, something the Generic Defendants have no control over. See *Mensing*, 131 S.Ct. at 2579 (“We can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it.”). But if “conjectures suffice to prevent” impossibility preemption, “it is unclear when ... the *Supremacy Clause* would have any force.” *Id.* (emphasis in original).

5

Plaintiffs insist that Generic Defendants could have simply removed alendronate sodium from the market. Whatever the merit of that contention, it is essentially a re-argument of *Mensing*. The Supreme Court unequivocally held that failure-to-warn claims against generic drug manufacturers are preempted by federal law. To accept Plaintiffs’ argument that Generic Defendants could have simply stopped marketing alendronate sodium, this Court would have to directly contravene binding law.

*7 Contrary to Plaintiffs’ assertions, the Food and Drug Administration Amendments Act (“FDAAA”) does not change this analysis. First, nothing in FDAAA alters *Mensing*’s analysis of the viability of sending Dear Doctor Letters. Specifically, FDA regulations still require that letters be “consistent with and not contrary to such approved or permitted labeling.” 21 C.F.R. 201.100(d)(1). Thus, Generic Defendants could not, without violating federal law, advise prescribing physicians of warning information different from that provided in the FDA-approved label. Second, FDAAA did not change the fact that the Generic Defendants still cannot unilaterally change their alendronate sodium labels. Under the amendments, once FDA “becomes aware of new safety information” that it “believes should be included in the labeling” of a drug, FDA must notify the reference-listed drug manufacturer. 21 U.S.C. § 355(o)(4)(A). Then the manufacturer must propose a change to the label reflecting the new safety information and the FDA must act upon this proposal. *Id.* § 355(a)(4)(B)-(C). Importantly, under this section, if the manufacturer of the branded drug is still

marketing the drug, as is the case here, FDA must first approach that manufacturer. *Id.* § 355(a)(4)(A). Only if the branded drug is no longer being marketed can the FDA require a generic manufacturer to propose a change. *Id.* And even if the Generic Defendants were to notify FDA of “new safety information,” there is no guarantee that the branded drug’s labeling would ultimately be changed. *See id.* § 355(o)(4)(C). Accordingly, the *Mensing* analysis is not affected by FDAAA because the Generic Manufacturers are still unable to unilaterally change drug labeling “without special permission and assistance, which is dependent on the exercise of judgment by a federal agency.” *Mensing*, 131 S.Ct. at 2581.

Plaintiffs advance several other theories as to why the failure-to-warn claims are not preempted. In their opposition brief, Plaintiffs argue that failure to update generic labeling to reflect labeling changes made to *Fosamax* are not preempted. Plaintiffs cite FDA Guidance that urges generic manufacturers to promptly implement labeling changes made by the corresponding branded drug. (Pl.’s Ex. F, “FDA, Guidance for Industry: Revising ANDA Labeling Following Revision of RLD Labeling” (2000)). Failure timely update generic labeling, one district court found, affects the *Mensing* preemption analysis. *See Fisher v. Pelstring*, No. 09-cv-00252, 2011 U.S. Dist. LEXIS 116162, 2011 WL 4552464 (D.S.C. Sept. 30, 2011). But in this case, Plaintiffs offer only pure conjecture to support the theory that Generic Defendants failed to promptly update alendronate sodium labeling. In their brief, Plaintiffs point out that defendants in the *metoclopramide* litigation admitted to lagging behind in label updates and that, in this case, the “failure of some or all Defendants to timely strengthen their warnings ... could have directly resulted in the prescription of Defendants’ *alendronate* sodium to Plaintiffs.” (Pl.’s Opp. Br. at 11–12; Doc. No. 296.) While there have been several updates to the *Fosamax* labeling, neither Plaintiffs’ briefing nor pleadings provide any facts to plausibly support the theory that Generic Defendants failed to update their labeling. That a failure to timely update alendronate sodium labeling “could have occurred” is nothing “more than a sheer possibility” and is not “sufficient to state a claim for relief.” *See Iqbal*, 129 S.Ct. at 1949.

*8 Finally, Plaintiffs’ brief advances the theory that Generic Defendants failed to effectively communicate warnings because they did not send Dear Doctor letters “highlighting” or “explaining” warning information. But Plaintiffs did not plead this claim, and instead raise it now only in their briefing. Plaintiffs plead only that the warnings were deficient

for failing to disclose of risks not already in alendronate sodium labeling. In other words, Plaintiffs’ pleadings only claim that the drug’s labeling was insufficient in substance; they do not “give fair notice” of any claim that what was in the labeling was sufficient but needed to be more effectively communicated. (Brown Compl. at ¶¶ 71–89.) Indeed, Plaintiffs’ complaints are entirely devoted to asserting that the Generic Defendants knew of the risk of *osteonecrosis* and bone damage but failed to include such information in *alendronate* sodium labeling. Thus, the gravamen of the failure-to-warn claims is that the *alendronate* sodium labeling should have been changed to include stronger warnings—a claim that is plainly preempted by federal law under *Mensing*.

4. Negligence

Plaintiffs’ negligence claims are also preempted. Plaintiffs allege that the Generic Defendants “failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution” of alendronate sodium. (Brown Compl. at ¶ 136.) First, an allegation that the labeling, marketing, and promotion failed to live up to a standard of ordinary care is preempted by *Mensing* for the reasons explained in the Court’s analysis of the failure-to-warn claims. This aspect of the negligence claim necessarily supposes that state law required Generic Defendants to have altered alendronate sodium labeling in order to conform to a standard of ordinary care, but *Mensing* held that because federal law imposes a “duty to keep the label the same,” it is impossible for manufacturers “to comply with both their state-law duty” and federal law. *Mensing*, 131 S.Ct. at 2587.

Second, Plaintiffs’ allegation of failure to exercise ordinary care in the design, testing, and manufacture fail for the reasons explain in this opinion’s analysis of the design and manufacturing defect claim sections. There is no factual support for the manufacturing defect claim. Additionally, *Mensing* demonstrates that a state tort duty requiring generic manufacturers to violate a federal duty of sameness is preempted. Here, Plaintiffs’ negligence claim necessarily alleges that Generic Defendants should have changed the active ingredient in its generic Fosomax, but such action is barred by FDA’s ANDA requirements. Thus, this state law claim is preempted.

5. Breach of Implied Warranty

The breach of implied warranty claims are preempted. Plaintiffs state that Generic Defendants “impliedly warranted

[alendronate sodium] to be of merchantable quality, fitness, and safe for such use" but that the drug "was not of merchantable quality" because it was "unreasonably dangerous." (Brown Compl. at ¶ 150–52.) Because this cause of action is reliant on the argument that alendronate sodium should have been designed differently, it fails for the reasons explained in the Court's analysis of the design defect claims. Pursuant to FDA's equivalence requirements of generic drugs, the Generic Defendants could not have changed the generic drug's active ingredient to be different from the active ingredient in *Fosamax*. But the breach of implied warranty claim necessarily alleges that manufacturers should have changed alendronate sodium's design. This would be in violation of the federal duty of sameness, and therefore, this claim is preempted.

6. Breach of Express Warranty, Fraud, Misrepresentation, Failure to Conform to Representation, Negligent Misrepresentation, and Violation of Consumer Protection Statutes

*9 These claims are preempted because the gravamen of these allegations is the insufficiency of *alendronate* sodium labeling. Each of these claims alleges that the Generic Defendants made false statements or representations that *alendronate* sodium was safe and effective for the treatment of *osteoporosis*. Throughout their complaints, Plaintiffs attack the accuracy of the *alendronate* sodium labeling. "Defendants' representations regarding the character and quality of [*alendronate* sodium] were untrue." (Brown Compl. at ¶ 159.) Further, Plaintiffs state that "Defendants describe and represent that their Product has characteristics that simply do not conform to reality." (*Id.* at ¶ 143.) The claims plead that the Generic Defendants should have changed or omitted the allegedly inaccurate or insufficient labeling information. See *Fisher v. Pelstring*, No. 09-cv-0252, 2011 U.S. Dist. LEXIS 116162, *14, 2011 WL 4552464 (D. S.C. September 30, 2011) (finding that plaintiff's breach of express warranty claim against generic drug manufacturer was preempted by *Mensing*).

But federal drug regulations forbid a generics manufacturer from unilaterally changing, omitting, or strengthening drug labeling. See *Mensing*, 131 S.Ct. at 2578 ("[S]tate law imposed on the Manufacturers a duty to attach a safer label to their generic [drug]. Federal law however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels."). Here, the Generic Defendants under federal law cannot unilaterally change or update their alendronate sodium labels and simultaneously conform to a state law duty that requires them to change those labels. Therefore, the federal duty of sameness conflicts with and consequently preempts the Plaintiffs' claims of breach of express warranty, fraud, misrepresentation, failure to conform to representation, negligent misrepresentation, and violation of consumer protection statutes.

7. Plaintiffs' Remaining Claims

Because judgment on the pleadings is granted in favor of Generic Defendants on Plaintiffs' state tort claims, including fraud and intentional wrongdoing, Plaintiffs' requests for restitution and claims of loss of consortium must also be dismissed. Both restitution and loss of consortium are dependent on the survival of Plaintiffs' state tort claims. However, *Mensing* preempts the state tort claims against Generic Defendants. Thus, Plaintiffs will not be able to recover restitution from Generic Defendants absent claims of fraud or intentional wrongdoing, nor can loss of consortium survive as a derivative claim.

III. CONCLUSION

For the reasons above, the Court grants the motion for judgment on the pleadings in favor of Generic Defendants as to Plaintiffs' state law claims. The Court denies the motion for judgment on the pleadings by the Watson Defendants. An appropriate order is filed herewith.

All Citations

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United States District Court,
S.D. New York.

In re GENERAL MOTORS LLC
IGNITION SWITCH LITIGATION.
This Document Relates to all Actions.

Nos. 14-MD-2543 (JMF), 14-MC-2543 (JMF).

Signed June 10, 2015.

OPINION AND ORDER

JESSE M. FURMAN, District Judge.

***1** This opinion addresses a thorny—and somewhat unsettled—issue in multi-district litigation (“MDL”): the effect of a consolidated complaint, brought on behalf of a putative class, on the underlying complaints of those not named in the consolidated complaint. It arises in the context of an MDL pending before this Court, relating to defects in the ignition switches and other features of certain General Motors vehicles and associated recalls. In complex MDLs like this one, involving hundreds of individual complaints and thousands of plaintiffs, consolidated complaints can be critical case management tools, helping to organize and clarify what claims and defenses are being pursued, thereby enabling the parties to conduct discovery more efficiently and providing an effective vehicle for motion practice with respect to common issues of law and fact. At the same time, however, a court presiding over an MDL must take steps to ensure that efficiency does not trump fundamental fairness and that the desire for certainty does not deprive any individual party of substantive rights. Having recently entered an Order clarifying the effect of consolidated complaints (the “Consolidated Complaints”) filed in this MDL on individual complaints (Order No. 50 (14-MD-2543 Docket No. 875), attached as Exhibit 1), the Court provides this Opinion to describe the background leading up to, and rationale behind, that Order—in the hopes that doing so will provide the parties and other courts presiding over complex MDLs with helpful guidance.¹

¹ This Opinion is intended to explain and supplement Order No. 50; it is not intended to modify or alter Order No. 50 in any way.

BACKGROUND

On June 12, 2014, the Judicial Panel on Multidistrict Litigation (the “JPML”) issued an order transferring fifteen actions to this Court for “coordinated or consolidated pretrial proceedings” pursuant to [Title 28, United States Code, Section 1407](#). (14-MD-2543 Docket No. 1). All actions pending before the JPML at the time of its initial Order asserted economic loss claims against General Motors, LLC (“New GM”) based on an ignition switch defect in certain General Motors vehicles, one that “causes the vehicle’s ignition switch to move unintentionally from the ‘run’ position to the ‘accessory’ or ‘off position, resulting in a loss of power, vehicle speed control, and braking, as well as a failure of the vehicle’s airbags to deploy.” (*Id.* at 1–2). Since then, the JPML has expanded the scope of actions transferred to this MDL to encompass personal injury and wrongful death claims (see Transfer Order (14-MD-2543 Docket No. 505) 1 n. 1), as well as economic loss claims based on both ignition switch defects and other alleged defects, on the theory that “there will be discovery that is common to the MDL and to” such actions (Transfer Order (14-MD-2543 Docket No. 519) 1). To date, the JPML has issued forty-seven transfer orders; the total number of cases in the MDL, including cases directly filed in this Court, is now up to 210, brought by several thousand Plaintiffs. New cases continue to be transferred to and filed in the MDL nearly every week.

***2** Complicating matters, when the JPML created this MDL, there was parallel litigation occurring before the United States Bankruptcy Court for the Southern District of New York arising out of the 2009 bankruptcy of the General Motors Corporation (now called Motors Liquidation Corporation) (“Old GM”). Specifically, New GM had filed several motions to enforce before Bankruptcy Judge Robert E. Gerber, seeking to enforce the terms of a Sale Order and Injunction entered on July 5, 2009 (the “Sale Order”), pursuant to which New GM purchased the majority of the assets of Old GM “free and clear” of many of Old GM’s liabilities. New GM argued that the Sale Order barred many of the claims being pursued in this MDL, including any claims against New GM based on successor liability. (See 09-BR-50026 (Bankr.S.D.N.Y.) Docket Nos. 2968, 12620). (On April 15, 2015, Judge Gerber ruled on New GM’s motions, holding that the Sale Order

does enjoin certain Plaintiffs' claims in their entirety and other Plaintiffs' claims to the extent that they rely on acts or conduct by Old GM. *See In re Motors Liquidation Co.*, 529 B.R. 510, 598 (Bankr.S.D.N.Y.2015). On June 1, 2015, Judge Gerber entered judgment and an order, pursuant to 28 U.S.C. § 158(d), and Fed. R. Bankr.P. 8006(e), certifying the judgment for direct appeal to the United States Court of Appeals for the Second Circuit. (09-BR-50026 (Bankr.S.D.N.Y.) Docket Nos. 13177, 13178). To date, at least three notices of appeal have been filed in connection with the judgment. (09-BR-50026 (Bankr.S.D.N.Y.) Docket Nos. 13179, 13180, 13185). Others are likely to follow.)

In that context, the Court entered Order No. 7 on August 7, 2014 (14-MD-2543 Docket No. 215), indicating that Lead Counsel should "review all existing complaints ... and file a consolidated or master complaint with claims on behalf of the class or classes [of economic loss Plaintiffs], as appropriate." (*Id.* at 2-3).² The Court explained that "having a consolidated or master complaint sooner rather than later would streamline and clarify the claims and help eliminate those that are duplicative, obsolete, or unreflective of developing facts or current law." (*Id.* at 3). In addition, the Court reasoned that having a consolidated or master complaint would not only facilitate litigation in this Court, but would also help in the management and adjudication of New GM's motions to enforce in the Bankruptcy Court. (*Id.*). In a subsequent Order (Order No. 8), entered eight days later, the Court set a schedule for the filing of a consolidated complaint, ordering that Lead Counsel for Plaintiffs make available to all MDL Plaintiffs a draft version of the complaint within forty-five days and that Lead Counsel file a final version within sixty days. (Order No. 8 (14-MD-2543 Docket No. 249) 5). The Court provided that any Plaintiff could file objections to the consolidated complaint, and ordered that any such objections must be filed within seven days of the filing of the complaint. (*Id.*).

² In Order No. 7, the Court expressed its view that consolidated or master complaints would be helpful only with respect to economic loss claims and complaints, and would not be "necessary or prudent with respect to personal injury and wrongful death claims" given, among other things, the likelihood of case-specific factual and legal issues. (Order No. 7, at 2). Accordingly, this Opinion and Order—like the Consolidated Complaints themselves—pertains only to economic loss claims and complaints.

*3 On October 14, 2014, Lead Counsel filed two Consolidated Complaints. (14-MD-2543 Docket Nos. 345, 347 (*errata* at 14-MD-2543 Docket No. 379)). The first—which (excluding counsels' signatures) is 649 pages long—is based on purchases or leases of General Motors vehicles before July 11, 2009, the effective date of the Sale Order (the "Pre-Sale Complaint"). (Consol. Class Action Compl. Against New GM Recalled Vehicles Manufactured By Old GM & Purchased Before July 11, 2009 (Docket No. 347)). The second, which is 686 pages long, is based on purchases or leases of General Motors vehicles after July 11, 2009 (the "Post-Sale Complaint"). (Consol. Compl. Concerning GM-Branded Vehicles Acquired July 11, 2009 Or Later (Docket No. 345)). Naturally, but significantly, the Consolidated Complaints did not name as Plaintiffs every single Plaintiff who had filed an economic loss claim in the MDL. Instead, each Complaint named only a subset of the economic loss Plaintiffs in this MDL as proposed class representatives (*see* Pre-Sale Compl. 9-45; Post-Sale Compl. 8-52), and indicated that it was brought on behalf of proposed nationwide classes of all persons who either bought or leased certain General Motors vehicles within specified time periods. (Pre-Sale Compl. 1; Post-Sale Compl. 7-8). Both Complaints also included a version of the following provision:

This pleading neither waives nor dismisses any claims for relief against any defendant not included in this pleading that are asserted by any other plaintiffs in actions that have been or will be made part of this MDL proceeding, except by operation of the class notice and (with respect to any Rule 23(b)(3) class) any opt-out provisions on claims or common questions asserted in this Complaint and certified by this Court.

(Post-Sale Compl. 1; *see* Pre-Sale Compl. 2 (similar)). No Plaintiffs objected to the Consolidated Complaints after their filing.

In advance of the status conference held on November 6, 2014, the parties indicated in a joint agenda letter that New GM took issue with the above-quoted language in the Consolidated Complaints, on the theory that "any purported

reservation of claims" was "inconsistent with and improper under this Court's Orders." (Joint Agenda Ltr. (Docket No. 376) at 4). At the conference, the Court noted that it had "come to [its] attention after the two consolidated complaints were filed [that] there is some ambiguity in the MDL world or MDL context with respect to what role the 'consolidated complaint' plays ... that is to say, whether these essentially supersede the individual complaints, at least until the time that remand comes into play, as would be the case in ordinary litigation with an amended complaint, or if [in] essence [they serve] some sort of administrative role more specific to the MDL context." (Nov. 6, 2014 Hr'g Tr. (Docket No. 414) 106). Lead Counsel agreed that the Consolidated Complaints were intended to have superseding rather than administrative effect—a distinction discussed below—and that they had reached a tentative agreement with New GM that "the complaints that are not in the consolidated complaint would be deemed dismissed without prejudice, and that [Plaintiffs] would be giv[en] a ... deadline for filing any amendments [Plaintiffs] want to make." (*Id.* at 107). The Court directed the parties to continue meeting and conferring about the issue—and to consider whether the Court should give all Plaintiffs an opportunity to be heard with respect to the Consolidated Complaints' effect on their underlying complaints. (*Id.* at 108–09).

*4 The Court revisited the issue at the next status conference, held on December 15, 2014. (Dec. 15, 2014 Hr'g Tr. (14-MD-2543 Docket No. 480) 16–39). Three days later, Lead Counsel and New GM submitted a joint proposed order regarding the Consolidated Complaints' effect on the underlying complaints; the Court entered the Order, designated Order No. 29, later that day. (Order No. 29 (14-MD-2543 Docket No. 477); Defs.' Resp. Opp'n Elliott, Sesay, & Bledsoe Pls.' Mot. Reconsideration MDL Order No. 29 (14-MD-2543 Docket No. 554) ("Defs.' Resp."), Ex. A). Order No. 29 provides, in relevant part, as follows:

[A]ny economic loss allegations, claims, and defendant(s) not included in the Consolidated Complaints are hereby dismissed without prejudice (1) upon the effective date of this Order for complaints already transferred to or filed in MDL 2543, and (2) 60 days following the date of transfer or filing for complaints that are transferred to or filed in MDL 2543 after the date of this Order but prior to June 4, 2015.... If any plaintiff whose claims are dismissed pursuant to this paragraph objects to dismissal of his or her allegations, claims, or any defendant(s) not named in the Consolidated Complaints, then such plaintiff may seek leave with the

Court to reinstate his or her allegations or claims or the addition of such dismissed defendant(s) upon a showing of good cause within 14 days of the dismissal without prejudice.

(Order No. 29 at 2–3). Attached to the Order as Exhibit A was a list of all the individual cases in the MDL asserting only economic loss claims (to be dismissed without prejudice in their entirety) or asserting mixed economic loss and personal injury claims (with respect to which the economic loss claims would be dismissed without prejudice).

The Order gave Lead Counsel until June 4, 2015 (since extended to June 12, 2015 (Apr. 24, 2015 Hr'g Tr. (Docket No. 944) 27)), to seek leave of Court to amend the Consolidated Complaints. (Order No. 29 at 3). Significantly, the paragraph immediately after the one quoted above also provided that "[a]ny claims and defendant(s) that are dismissed *without* prejudice and reinstated pursuant to the preceding paragraph, but which are not included in any amendment of the Consolidated Complaints filed by June [12], 2015, shall be deemed dismissed *with* prejudice as of the later of (a) June [12], 2015 or (b) 90 days following the date the complaint is transferred to or filed in MDL 2543." (*Id.* (emphasis added)). Finally, "[f]or any complaint transferred to or filed in MDL 2543 after June [12], 2015 (a 'Post–June [12], 2015 Complaint')," Lead Counsel were granted sixty days following the transfer or filing to seek leave to amend the Consolidated Complaints to add factual matter, claims, or defendants included in the underlying complaint. (*Id.* at 3–4). If Lead Counsel did not seek such leave to amend, or if the requested amendment was denied by the Court, "then any allegations, claims, and/or defendant(s) in the Post–June [12], 2015 Complaint not included in the Consolidated Complaints shall be dismissed *with* prejudice at the expiration of the 60-day period or the Court's order denying the amendment, whichever occurs first." (*Id.* at 4 (emphasis added)).

*5 On January 2, 2015, Gary Peller—counsel for Plaintiffs in *Elliott, et al. v. General Motors LLC, et al.*, 14-CV-8382; *Sesay, et al. v. General Motors LLC, et al.*, 14-CV-6018; and *Bledsoe, et al. v. General Motors LLC, et al.*, 14-CV-7631—filed a motion for reconsideration of Order No. 29 and, in the alternative, an objection to dismissal of his clients' claims pursuant to the procedures set forth in that Order. (14-MD-2543 Docket Nos. 491, 494). Mr. Peller argued, among other things, that (1) dismissal of individual Plaintiffs' claims pursuant to Order No. 29 threatened their due process rights (Mem. Law Supp. Reconsideration Order No. 29 *Elliott, Sesay, & Bledsoe* Pls. (14-MD-2543 Docket

No. 502) (“Peller Mem”) 4, 19); and (2) that most MDL courts do not treat consolidated complaints as superseding individual complaints and, in any event, do not dismiss claims of those plaintiffs not named in the consolidated complaints (*id.* at 20–24). Mr. Peller also noted that, because the parties’ joint proposed order entered by the Court had been submitted by Lead Counsel, not by Mr. Peller, and—pursuant to the Court’s Individual Rules and Practices in Civil Cases, as well as Section VII of Order No. 8—had not been submitted on ECF, he had not had an opportunity to be heard on its contents. (*Id.* at 17 n. 34). Notably, no other Plaintiffs objected to dismissal of their cases or claims.

The Court heard from the parties and Mr. Peller at the status conference held on March 13, 2015. (See March 13 Hr’g Tr. (14-MD-2543 Docket No. 686) 61–83). Following discussion of Mr. Peller’s motion and objection, the Court reinstated the *Elliott*, *Sesay*, and *Bledsoe* Plaintiffs’ claims and indicated that it planned to enter an amended order modifying and clarifying the effects of the Consolidated Complaints on underlying cases, effectively granting Mr. Peller’s motion for reconsideration. (*Id.*.; Order No. 39 (14-MD-2543 Docket No. 671) § VII). The Court directed the parties, in consultation with Mr. Peller, to submit an agreed-upon proposed amended order or competing orders (*id.*), which the parties did three weeks later. (See 14-MD-2543 Docket Nos. 809, 810). After reviewing the parties’ submissions, the Court drafted its own proposed order—incorporating aspects of both sides’ proposals—and gave the parties an opportunity to be heard with respect to the proposed order at the status conference held on April 24, 2015. (14-MD-2543 Docket No. 855). After the parties indicated that they had no objection to (or suggestions for) the proposed order (Apr. 24, 2015 Hr’g Tr. 29) the Court entered an amended version of Order No. 29—namely, Order No. 50—later that day. (14-MD-2543 Docket No. 875).

Order No. 50 preserves Order No. 29 in one respect: It provides that any economic loss claims and complaints filed in the MDL as of the date of Order No. 29 that had been dismissed without prejudice pursuant to that Order (that is, all underlying economic loss claims and complaints except for the *Elliott*, *Bledsoe*, and *Sesay* complaints, which had been reinstated on March 13, 2015) remain dismissed. (*Id.* ¶ 6). Additionally, the Order establishes a system whereby individual economic loss complaints are dismissed without prejudice within a certain time after their direct filing in, or transfer to, the MDL, after Plaintiffs are granted an opportunity to object. Finally, and significantly, the Order

clarifies that its provisions “do not extinguish the claims of individual plaintiffs in the event class certification is denied, or the presentation of claims by individual plaintiffs who exclude themselves from any class that is certified, under procedures to be prescribed by the Court (after hearing from the parties) in connection with its class certification determinations.” (*Id.* ¶ 3). The Order further clarifies that all dismissals pursuant to the procedures of the Order are without prejudice, and tolls the statute of limitations for all Plaintiffs until the class certification phase. Like Order No. 29, therefore, Order No. 50 is intended to facilitate management of the MDL by clarifying that the Consolidated Complaints do supersede individual complaints for purposes of pretrial proceedings (including motion practice) and ensuring that the parties do not have to file or litigate motions in hundreds of individual cases. At the same time, Order No. 50 is intended to ensure that the administrative convenience provided by the Consolidated Complaints does not come at the expense of the substantive rights of any Plaintiffs not named in the Complaints.

*6 When the Court granted Mr. Peller’s motion for reconsideration of Order No. 29 at the March 13, 2015 status conference, it indicated it might issue a written opinion supplementing its oral reasons for granting the motion, on the theory that explaining the process and rationale behind entry of what became Order No. 50 might prove useful to the parties in this MDL and to courts and parties involved in other complex civil litigation. (See Order No. 39 § VII). This is that opinion.

DISCUSSION

Title 28, United States Code, Section 1407(a), enacted in 1968, provides that “when civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings.” 28 U.S.C. § 1407(a). Such transfer is warranted when the JPML finds that it would “be for the convenience of parties and witnesses and ... promote the just and efficient conduct of such actions.” *Id.* Promoting “the just and efficient conduct of such actions,” however, is not necessarily an easy task, especially when, as here, MDLs involve hundreds of independent actions brought by thousands of plaintiffs. “For it all to work, multidistrict litigation assumes cooperation by counsel and macro-, rather than micro-, judicial management because otherwise, it would be an impossible task for a single district judge to

accomplish.” *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir.2006) (hereinafter, “*In re PPA*”). A district court must be afforded “broad discretion to administer the [MDL] proceeding as a whole,” because “multidistrict litigation is a special breed of complex litigation where the whole is bigger than the sum of its parts.” *Id.* at 1232.

Even as it engages in “macro” judicial management, an MDL court must not lose sight of the fact that an MDL is comprised of individual actions brought on behalf of individual litigants, each with his or her (or its) own—sometimes unique—rights and interests. Moreover, for at least some actions and litigants, the MDL will serve as a way station rather than a final destination. That is, although many MDLs ultimately result in some form of a global settlement, not all do; and those that do settle often include cases with unique issues or claims that are not resolved by the global settlement or plaintiffs that are not within the scope of, or opt out of, the certified class or classes. Significantly, pursuant to the terms of [Section 1407](#), if any case or claim remains unresolved at the conclusion of pre-trial proceedings, it must be remanded back to the federal court from which it was transferred (absent a waiver). Indeed, in the seminal case *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 31, 40, 118 S.Ct. 956, 140 L.Ed.2d 62 (1998), the Supreme Court re-affirmed the JPML’s obligation, under [Section 1407](#), to remand any cases not terminated before the conclusion of pre-trial proceedings—and, in doing so, invalidated a JPML rule permitting transferee courts to assign a member case to itself for trial. It follows that there is a fundamental tension embedded in MDLs—between, on the one hand, facilitating effective motion practice, discovery, and resolution of *all* claims present in the MDL while, on the other hand, acknowledging (for purposes of eventual remand and otherwise) the individual character of all of the actions before an MDL Court. Nowhere is that tension more apparent than in MDL courts’ different treatment of consolidated or master complaints.

*7 Consolidated or master complaints are not specifically mentioned in the Federal Rules of Civil Procedure. Nevertheless, courts have interpreted Rule 42(a), which authorizes district courts to consolidate actions and to make such orders “as may tend to avoid unnecessary costs or delay,” to authorize the filing of such complaints. See *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 141 (E.D.La.2002) (citing *Katz v. Realty Equities Corp. of N. Y.*, 521 F.2d 1354 (2d Cir.1975), and other cases). MDL courts differ, however, in the treatment they afford to consolidated complaints. Some

judges have elected to treat consolidated complaints merely as an “administrative summary” of the claims to be presented, without an independent legal existence or effect. See *In re Refrigerant Compressors Antitrust Litig.*, 731 F.3d 586, 590 (6th Cir.2013) (noting that in many MDLs, “the master complaint is not meant to be a pleading with legal effect but only an administrative summary of the claims brought by all the plaintiffs”). “When plaintiffs file a master complaint of this variety, each individual complaint retains its separate legal existence.” *Id.*; see also *In re Nuvaring Prods. Liab. Litig.*, No. 08-MD-1964 (RWS), 2009 WL 2425391, at *2 (E.D.Mo. Aug.6, 2009) (concluding that “the filing of the master consolidated complaint in this action was simply meant to be an administrative tool to place in one document all of the claims at issue in this litigation,” and was not intended to be the subject of Rule 12(b) motion practice). Courts have adopted such an approach based on the concern that “a master complaint, if given the status of a traditional complaint, could be used to circumvent the remand requirement of [28 U.S.C. § 1407](#) by substituting itself for all individual actions filed in the MDL and thereby frustrate the intended effect of that statute as recognized in [Lexecon].” *In re Propulsid*, 208 F.R.D. at 141.

Alternatively, as the Supreme Court recently noted, parties in an MDL “may elect to file a ‘master complaint’ and a corresponding ‘consolidated answer,’ which supersede prior individual pleadings.” *Gelboim v. Bank of Am. Corp.*, — U.S. —, — n. 3, 135 S.Ct. 897, 904 n. 3, 190 L.Ed.2d 789 (2015). “In such a case, the transferee court may treat the master pleadings as merging the discrete actions for the duration of the MDL pretrial proceedings.” *Id.* Under such an approach, the court treats the consolidated pleadings as “legally operative” and—should there be motion practice—may treat them as dispositive with respect to the common legal and factual issues that motivated the underlying cases’ transfer to the MDL in the first instance. See *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 27 F.Supp.3d 447, 484 (S.D.N.Y.2014). Particularly in large—and ever-expanding—MDLs like the one before this Court, the benefits of treating consolidated complaints as “superseding” are clear: It assists in “streamlining the litigation,” *In re Global Crossing, Ltd. Sec. Litig.*, No. 02-CV-910 (GEL), 2004 WL 2584874, at *3 (S.D.N.Y. Nov.12, 2004); “controls the course and scope of the proceedings,” *In re Katrina Canal Breaches Litig.*, 309 F. App’x 836, 838 (5th Cir.2009) (per curiam) (internal quotation marks omitted); and facilitates efficient motion practice, see generally *In re WorldCom, Inc. Sec. Litig.*, No. 03-CV4498 (DLC), 2005 WL 2403856, at *3 (S.D.N.Y. Sept.30, 2005).

*8 Like snowflakes, no two MDLs are exactly alike and, no doubt, whether to require the filing of a consolidated complaint and, if so, whether to treat such a complaint as “administrative” or “superseding” will depend on the particulars of a given MDL. Thus, it is critical that the parties and the court make clear what species of pleadings are being used. Cf. *Refrigerant Compressors Antitrust Litig.*, 731 F.3d at 591 (“The use of one term to describe two different types of pleadings leads to confusion.... Plaintiffs often file something labeled a ‘master complaint’ without saying whether they mean to file an operative pleading or an administrative summary, prompting satellite litigation about the status of the documents submitted to the court”). Where a consolidated complaint is intended to be legally operative, it is also critical for the court to make clear precisely what effect the filing of the consolidated complaint has on the underlying complaints so that the parties can take whatever steps are necessary to protect and preserve their substantive rights. To streamline the litigation and eliminate duplicative claims and complaints, dismissal of the underlying complaints may be the preferred approach. See, e.g., *Global Crossing*, 2004 WL 2584874, at *3 (“[G]iven the desirability of streamlining the litigation and eliminating duplicative cases that serve no purpose in light of the class actions being vigorously pursued by Lead Plaintiffs ... the Court has put plaintiffs and their attorneys on clear notice that they must advise the Court, within a specified time limit, whether they object to consolidation and/or whether, after consolidation is ordered, they continue to see a rationale for pursuing a separate complaint, on pain of dismissal. The vast majority of plaintiffs have elected to withdraw their complaints in accordance with the consolidation order, and have consented to dismissal; a handful have timely stated reasons why their complaints, though consolidated with the principal action for pretrial purposes, should not be dismissed.”); *In re Ford Motor Co. Speed Control Deactivation Switch Prods. Liab. Litig.*, 664 F.Supp.2d 752, 770 (E.D.Mich.2009) (“*Ford SCDS*”) (dismissing “claims and defendants not enumerated” in the consolidated complaint). But a court must make clear whether (and when) dismissal is *without* prejudice or *with* prejudice.

The former option—dismissal *without* prejudice—helps ensure that the rights and interests of individual parties will not be inadvertently compromised. After all, an individual plaintiff can always seek to reinstate his or her lawsuit depending on what happens in the MDL (in particular, depending on what happens in the class certification phase of the MDL). At the same time, dismissing *without* prejudice

poses some risk to the principles of efficiency, certainty, and finality, as the parties in an underlying case could, in theory, sit idly by while discovery and motion practice take place with respect to the consolidated complaint only to reemerge and demand to start at (or near) square one. See *Ford SCDS*, 664 F.Supp.2d at 769 (concluding that dismissal of underlying complaints with prejudice was appropriate because “[a]llowing plaintiffs to silently pursue claims and parties not included in the [master complaint] poses substantial uncertainty in these proceedings, ... contrary to the purpose of the MDL process”). By contrast, dismissal with prejudice provides more certainty and closure. But it is plainly in some tension with the proposition that consolidation pursuant to Section 1407 is for “pre-trial” purposes only. Cf. *Refrigerant Compressors Antitrust Litig.*, 731 F.3d at 592 (holding that the filing of a consolidated complaint had the effect of merging the consolidated actions, but only for “the duration of the pretrial proceedings,” and emphasizing that “when the pretrial phase ends and cases not yet terminated return to their originating courts for trial [under Section 1407], the plaintiffs' actions [would] resume their separate identities”).

*9 Further, if premature, dismissal with prejudice can also jeopardize an individual party's rights and interests. For example, if an underlying complaint is dismissed before the class certification stage, the plaintiff in that action cannot know whether he or she would want to opt out of a class (assuming a class is even ultimately certified and that the plaintiff would fall within the scope of the class) and go it alone, leaving him or her in the difficult position of not knowing whether to take steps to protect his or her rights. Additionally, a dismissed party's claims are arguably extinguished, potentially precluding any recovery even in the event of a settlement. See, e.g., *Samuels v. N. Telecom, Inc.*, 942 F.2d 834, 836 (2d Cir.1991) (“A dismissal with prejudice has the effect of a final adjudication on the merits favorable to defendant and bars future suits brought by plaintiff upon the same cause of action.”) (internal quotation marks omitted); *Petition of Shavit*, 197 B.R. 763, 768 (Bankr.S.D.N.Y.1996) (noting that “a dismissal with prejudice is a complete adjudication on the merits, with *res judicata* effect,” and accordingly “operates to bar another action on the claim that was so dismissed” (internal quotation marks omitted)). Given that dismissal with prejudice is “a harsh remedy and is appropriate only in extreme situations,” *Lucas v. Miles*, 84 F.3d 532, 535 (2d Cir.1996), it should not be undertaken lightly or prematurely.

Upon reflection, those were the problems created by this Court's original order regarding the effect of the Consolidated Complaints—Order No. 29. As discussed above, that Order provided that, upon the filing of amended Consolidated Complaints by Lead Counsel (now due on June 12, 2015), any “claims and defendant(s)” reinstated pursuant to the procedures set forth in the Order but not included in the amended Consolidated Complaints would be dismissed *with* prejudice. (Order No. 29 at 3).³ The Order, however, provided no formal means by which a Plaintiff whose claims were left out of the amended Consolidated Complaints could object to Lead Counsel's omission, let alone object to dismissal of his or claims. Equally important, because such dismissal was *with* prejudice, the Order had the unintended effect of potentially compromising the substantive rights of Plaintiffs whose claims were not included in the amended Consolidated Complaints. That is, by virtue of being left out of the amended Consolidated Complaints, a Plaintiff might have been barred from pursuing his or her claims if a class was not ultimately certified; precluded from participating in—or recovering as part of—any class if ultimately certified; and prevented from opting out of a class and pursuing his or her claims separately if a class were ultimately certified. In essence, therefore, Order No. 29 inadvertently left the fate of certain economic loss Plaintiffs in the hands of Lead Counsel: If Lead Counsel named a Plaintiff or included that Plaintiff's claims in the amended Consolidated Complaint, then that Plaintiff's rights would be protected and pursued; if Lead Counsel did not, then that Plaintiff's rights might be extinguished.⁴

³ Strictly speaking, Order No. 29 was silent with respect to the ultimate fate of complaints and claims that had been dismissed without prejudice but *not* reinstated. It stands to reason that those complaints and claims would not have been treated more favorably than complaints and claims that had been reinstated upon a showing of good cause, so presumably they too would have been dismissed with prejudice. The Court need not resolve the issue, however, as Order No. 29 has been superseded by Order No. 50.

⁴ The same was true of Order No. 29 with respect to Plaintiffs whose complaints are transferred to this MDL after the June amendment deadline: If Lead Counsel sought leave to amend the Consolidated Complaints again to include the claims of those Plaintiffs, then their rights would be preserved;

if not, or if the proposed amendment was denied by the Court, then any claims brought in their individual complaints would be dismissed with prejudice. (Order No. 29 at 3–4).

***10** One solution to those problems, of course, would have been to require Lead Counsel to name every individual Plaintiff in the amended Consolidated Complaints or to include every underlying claim or theory in the amended Consolidated Complaints. *See, e.g., In re Mortg. Elec. Registration Sys. (MERS) Litig.*, No. 09-MD-2119 (JAT), 2011 WL 251453, at *11 (D.Ariz.Jan.25, 2011) (directing the plaintiffs, “if they choose to seek leave to amend, to jointly file a proposed consolidated amended complaint together with the various plaintiffs whose actions are currently joined to this MDL”); *see In re Mortg. Elec. Registration Sys. (MERS) Litig.*, 09-MD-2119 (D.Ariz.) Docket No. 1424, Ex. 3 (naming, in the consolidated amended complaint (“C AC”), what appear to be most if not all of the plaintiffs currently in the MDL); *see also In re Mortg. Elec. Registration Sys. (MERS) Litig.*, No. 09-MD-2119 (JAT), 2011 WL 4550189, at *1 (D.Ariz.Oct.3, 2011) (noting that defendants' motions sought “to dismiss all seventy-two member cases which were directed to join the CAC”). In the Court's view, however, that “solution” would have caused even bigger problems. For one thing, it would run counter to the well-established principle that plaintiffs (here, represented by Lead Counsel) are “the masters of their complaints.” *Standard Fire Ins. Co. v. Knowles*, —U.S. —, —, 133 S.Ct. 1345, 1350, 185 L.Ed.2d 439 (2013). Additionally, given the number of parties and the complexity of the issues in this MDL, such a requirement would have resulted in amended Consolidated Complaints that were significantly more unwieldy and complex than the existing Consolidated Complaints (which—at 649 and 686 pages—are already pushing the envelope on the “short and plain statement” requirements of **Rule 8 of the Federal Rules of Civil Procedure**). Finally, and perhaps most significantly, although requiring Lead Counsel to file “kitchen sink” amended Consolidated Complaints might protect the rights of all individual Plaintiffs, doing so would significantly compromise the efficiency that the MDL process was intended to provide. Among other things, it would inevitably require litigation of claims or theories that might not ultimately be pursued—and by lawyers not necessarily committed to those claims or theories to boot.

Instead of taking that suboptimal approach, the Court tried to strike a more appropriate balance in the Order that superseded Order No. 29—namely, Order No. 50. Like Order No. 29, Order No. 50 makes clear that the Consolidated Complaints

(and the anticipated amended Consolidated Complaints) are legally operative—that is, that they are intended to be superseding rather than administrative. (Order No. 50 ¶ 5). Additionally, in the interests of efficiency and certainty, Order No. 50 reaffirms that any complaint or claim that was previously dismissed and not reinstated pursuant to the procedure set forth in Order No. 29 remains dismissed. (*Id.* ¶ 6). Unlike Order No. 29, however, Order No. 50 provides that “all dismissals are, unless and until the Court orders otherwise, without prejudice.” (*Id.* at 1). It also gives Plaintiffs whose claims are not included in the amended Consolidated Complaints an opportunity to be heard by Lead Counsel and to object to dismissal of their claims. (*See id.* at 1; *see also id.* ¶ 8). And finally, in order “to protect the due process rights of economic loss plaintiffs,” it expressly provides that “dismissal of their individual complaints in order to streamline these proceedings does not preclude such plaintiffs from (a) recovering as a member of any class that might be certified or (b) pursuing claims, should a plaintiff choose to do so, if no class is certified or if the plaintiff opts out of a class that is certified.” (*Id.* at 1; *see also id.* ¶ 3 (“The provisions of this Order do not extinguish the claims of individual plaintiffs in the event class certification is denied, or the presentation of claims by individual plaintiffs who exclude themselves from any class that is certified, under procedures to be prescribed by the Court (after hearing from the parties) in connection with its class certification determinations.”)).

*11 Admittedly, in light of those provisions, Order No. 50 does not provide the same degree of finality or certainty that Order No. 29 provided. More specifically, in New GM’s words, it does increase the risk of an individual Plaintiff “sit[ting] on the sidelines for a period of months or years, and then seek[ing] to force defendants to relitigate issues that already have been decided and to repeat activities that already have occurred.” (Apr. 3, 2015 Ltr. (14-MD-2543 Docket No. 810) 5). In the Court’s view, however, that is the price that must be paid to ensure that the due process rights of individual Plaintiffs are not trampled in the name of efficiency. Moreover, Order No. 50 contains several provisions intended to mitigate and address such risks and help ensure that the MDL process will “promote the just and efficient” resolution of all member actions. *See 28 U.S.C. § 1407.* First, the Order provides that any ruling made with respect to the Consolidated Complaints “shall apply” to non-consolidated actions (that is, underlying complaints) unless a party shows cause, upon the motion of any party, why the ruling should not apply. (Order No. 50 ¶ 12). Second, the Order directs the parties to propose an additional order

“to be entered after Plaintiffs file the amended Consolidated Complaints to ensure that motion practice and discovery with respect to common issues of fact and law are conducted as part of these MDL proceedings.” (*Id.* ¶ 9). Through that order, the Court can and will take steps to ensure that a party cannot “sit on the sidelines” and expect to get discovery that could have and should have been obtained through the MDL and that motion practice with respect to common issues of law and fact is conducted by this Court as part of the MDL.

Finally, Order No. 50 contemplates further orders (including the possibility of dismissal of non-consolidated claims and complaints with prejudice) at or around class certification stage. At that point, it will presumably be clear whether a class will be certified; and if so, whether a particular Plaintiff falls within the scope of the certified class. Thus, individual Plaintiffs will be able to take whatever steps are necessary to preserve and protect their claims with a better understanding of the consequences if they fail to do so. As New GM notes, that does mean that certain important issues remain unresolved. (Apr. 3, 2015 Ltr. (14-MD-2543 Docket No. 810) at 5). But absent a better sense of what will occur at the class certification phase—including whether any class certification decisions by this Court will be appealed (*see* Apr. 3, 2015 Ltr. (14-MD-2543 Docket No. 809) 4)—setting procedures at this stage of the litigation would be premature at best and prejudicial to the parties at worst. Accordingly, to protect the rights of plaintiffs and to avoid setting deadlines that would almost inevitably be subject to change, Order No. 50 provides that the Court will set such procedures “in connection with its class certification determinations,” not now. (Order No. 50 ¶ 3).

CONCLUSION

*12 In complex, multidistrict litigation of this sort, courts must grapple with—indeed, juggle—a host of challenges and considerations. Among the most important of those challenges and considerations is striking the right balance between, on the one hand, protecting and preserving the rights and interests of individual litigants while, on the other hand, ensuring that such solicitude does not undermine the central purpose of MDL consolidation—namely, promoting “just and efficient” resolution of the parties’ disputes. *28 U.S.C. § 1407(a).* In its effort to streamline the litigation, the Court’s initial order addressing the effect of the Consolidated Complaints in this MDL—Order No. 29—failed to grant appropriate weight to the former concern. For the reasons

stated above, however, the Court concludes that Order No. 50—a copy of which is attached for ease of reference—does strike the right balance.

As noted, Order No. 50 contemplates entry of additional orders touching on these issues. Through those orders and others, the Court will undoubtedly refine the balance between the individual and collective even further. For now, however, the Court finds that Order No. 50 appropriately protects the interests of all individual parties while ensuring that the Court is able to “expeditiously and thoroughly resolve” the common legal and factual issues that motivated the JPML to transfer these cases here. *In re Asbestos Cases of Hatch, James & Dodge, G. Patterson Keahey*, No. 06-CV-741 (TS), 2007 WL 582983, at *2 (D.Utah Feb.20, 2007).

SO ORDERED.

EXHIBIT 1

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

IN RE: GENERAL MOTORS LLC IGNITION SWITCH
LITIGATION

This Document Relates To All Actions

JESSE M. FURMAN, United States District Judge:

14-MD-2543 (JMF)

14-MC-2543 (JMF)

ORDER NO. 50

[Reconsidering and Amending Order No. 29 Regarding the Effect of the Consolidated Complaints]

This matter is before the Court on the motion of the *Elliott*, *Sesay* and *Bledsoe* plaintiffs to reconsider Order No. 29 (14-MD-2543 Docket No. 477), regarding the effect on the claims of economic loss plaintiffs of consolidated complaints filed by Lead Counsel pursuant to Order No. 7 on October 14, 2014 (14-MD-2543, Docket Nos. 345, 347), and any amendments to those Consolidated Complaints pursuant to the procedures set forth below. As noted in Order No. 39 (14-

MD-2543 Docket No. 671), the motion for reconsideration is GRANTED.

Specifically, upon due consideration of the parties' submissions and proposed orders (14-MD-2543 Docket Nos. 809, 810; *see also* 14-MD-2543 Docket Nos. 502, 553, 554, 571), and having given the parties an opportunity to comment on the Court's own proposed order (*see* Order No. 49, 14-MD-2543 Docket No. 855), the Court determines that Order No. 29 should be: (1) clarified to specify that all dismissals are, unless and until the Court orders otherwise, without prejudice; (2) modified to provide a procedure to allow certain economic loss plaintiffs not named in the amended Consolidated Complaints to challenge the dismissal of their claims; and (3) revised to protect the due process rights of economic loss plaintiffs, such that dismissal of their individual complaints in order to streamline these proceedings does not preclude such plaintiffs from (a) recovering as a member of any class that might be certified or (b) pursuing claims, should a plaintiff choose to do so, if no class is certified or if the plaintiff opts out of a class that is certified.

*13 Accordingly, this Order supersedes Order No. 29 in its entirety, except that Order No. 29 remains intact insofar as it dismissed, without prejudice, the allegations, claims, and defendant(s) included in complaints that already had been transferred to or were filed in MDL 2543 as of the date of entry of that Order and not included in the Consolidated Complaints, which complaints were listed in Order No. 29, Exhibit A. (*See* 14-MD-2543 Docket No. 477; *see ¶ 6, infra*).

Background

In Order No. 7, the Court directed Lead Counsel to review all the existing complaints and “file a consolidated or master complaint with claims on behalf of the class or classes, as appropriate. After doing so, any counsel who believed that their claims should have been included, but were not, would have an opportunity to object.” The Court’s intent was that the Consolidated Complaints “would streamline and clarify the [economic loss] claims and help eliminate those that are duplicative, obsolete, or unreflective of developing facts or current law.” (Order No. 7 (14-MD-2543 Docket No. 215) at 3). In Order No. 8, the Court set a schedule for filing the Consolidated Complaints, which provided opportunities for other plaintiffs’ counsel to submit comments on the draft Consolidated Complaints and to object to the

final Consolidated Complaints. (Order No. 8 (14-MD-2543 Docket No. 249) at 5).

On October 14, 2014, Lead Counsel filed two Consolidated Complaints (14-MD-2543 Docket Nos. 345, 347). The first Consolidated Complaint asserts economic loss claims concerning GMbranded vehicles (manufactured by either General Motors Corporation (“Old GM”) or General Motors LLC (“New GM”)) that were acquired July 11, 2009 or later. The second Consolidated Complaint asserts economic loss claims for owners of vehicles manufactured by Old GM and purchased before July 11, 2009. In each, New GM was the sole defendant. Each of the Consolidated Complaints includes the following caveat:

This pleading neither waives nor dismisses any claims for relief against any defendant not included in this pleading that are asserted by any other plaintiffs in actions that have been or will be made part of this MDL proceeding, except by operation of the class notice and (with respect to any 23(b)(3) class) any opt-out provisions on claims or common questions asserted in this Complaint and certified by this Court.

(14-MD-2543 Docket No. 345 at 1; 14-MD-2543 Docket No. 347 at 2). The Consolidated Complaint as to vehicles manufactured by Old GM and purchased before July 11, 2009, further alleges that “[c]ertain claims for certain parties may, consistent with 28 U.S.C. § 1407 and the caselaw thereunder, be matters for determination on remand by transferor courts.” (14-MD-2543 Docket No. 347 at 2).

The Court and certain of the parties are concerned that the above language in the Consolidated Complaints may create ambiguity as to the status of economic loss claims not asserted in the Consolidated Complaints. To clarify the effect of the Consolidated Complaints (and any amended Consolidated Complaints) on claims asserted in these MDL proceedings, the Court makes the following findings and adopts the following procedures.

General Provisions

*14 1. In its June 9, 2014 Transfer Order transferring the MDL 2543 proceedings to this Court, the Judicial Panel on Multidistrict Litigation found that “[c]entralization under Section 1407 will eliminate duplicate discovery; prevent inconsistent pretrial rulings, including with respect to class certification; and conserve the resources of the parties, their counsel, and the judiciary.” *In re: General Motors LLC Ignition Switch Litigation*, 26 F.Supp.3d 1390, 1391 (J.P.M.L.2014).

2. Order Nos. 7, 29, and this Order were and are intended to streamline and simplify the operation and management of MDL 2543 by reducing the need of the parties to file or respond to (and the Court to decide) pretrial motions in multiple underlying complaints. The Consolidated Complaints and their amendments are intended to bring together common allegations and claims asserted by economic loss plaintiffs in these MDL proceedings. The Consolidated Complaints have been, and will continue to be, critical tools to organize and conduct motion practice, both here and in the Bankruptcy Court, to address class certification, and to manage the discovery process. They are the operative pleadings for these purposes.

3. The provisions of this Order do not extinguish the claims of individual plaintiffs in the event class certification is denied, or the presentation of claims by individual plaintiffs who exclude themselves from any class that is certified, under procedures to be prescribed by the Court (after hearing from the parties) in connection with its class certification determinations.

Procedures for Dismissal Without Prejudice

4. As stated on the record at the status conference earlier today, Lead Counsel has until June 12, 2015 (*i.e.*, almost six weeks after May 5, 2015, the expected date for substantial completion of Phase One discovery pursuant to Order No. 20) to amend the Consolidated Complaints based upon discovery or other developments in the case, including the April 15, 2015 ruling—and any subsequent rulings—by the Bankruptcy Court. Thereafter, it shall be presumed that no further amendment will be permitted, except upon good cause shown as to factual matters and claims that are thereafter revealed by discovery or alleged for the first time in cases

that are transferred to or filed in the MDL after the above-described deadline.

5. The Court has designated the Consolidated Complaints as the operative class action complaints in these MDL 2543 proceedings. The Court entrusts Lead Counsel with the identification and appropriate pleading of common claims asserted in the lawsuits consolidated in this MDL, after consultation with other plaintiffs' counsel, subject to the procedures for objections to be described in the paragraphs and sub-paragraphs below. Accordingly:

(a) By joining the Consolidated Complaints, those plaintiffs named in the Consolidated Complaints have amended their prior pleadings, and—to the extent they were not already dismissed pursuant to the terms of Order No. 29—their underlying complaints are dismissed without prejudice. The underlying complaints of any plaintiffs added to any amended Consolidated Complaints (see ¶ 4, *supra*) will be deemed dismissed on the date of the submission of those Complaints (see ¶ 7, *infra*).

*15 (b) Lead Counsel shall provide a copy of any draft amended Consolidated Complaints by secure electronic means to counsel for each economic loss plaintiff fourteen (14) days prior to the amendment deadline. Plaintiffs' counsel will provide Lead Counsel with any comments or proposed changes seven (7) days prior to the amendment deadline.

(c) Plaintiffs will have fourteen (14) days from the filing of the amended Consolidated Complaints to object and Lead Counsel shall have fourteen (14) days to respond. Any such objections and responses shall not exceed five (5) single-spaced pages and shall be filed in both 14-MD-2543 and 14-MC-2543. No replies shall be allowed without leave of Court.

6. With respect to complaints filed in or transferred to this MDL before December 18, 2014, allegations, claims, and defendant(s) not included in the Consolidated Complaints, as well as the complaints of plaintiffs not named in the Consolidated Complaints, were dismissed without prejudice effective December 18, 2014. (See Order No. 29, Ex. A). The time to object to that dismissal without prejudice of the cases identified on Order No. 29, Exhibit A having passed, all of those complaints—with the sole exceptions of the *Elliott*, *Bledsoe*, and *Sesay* complaints, which were reinstated by the

Court on March 13, 2015 (see Order No. 39 (14-MD-2543, Docket No. 671) § VII)—remain dismissed.

7. With respect to complaints filed in or transferred to this MDL since December 18, 2014, up until the time of the filing of the amended Consolidated Complaints, any allegations, claims and defendant(s) that are not included in the amended Consolidated Complaints shall be deemed dismissed without prejudice with respect to the plaintiffs named in such amended Consolidated Complaints; and any allegations, claims and defendant(s) shall be deemed dismissed without prejudice with respect to plaintiffs who are not named in such amended Consolidated Complaints, unless such plaintiff not named in the Consolidated Complaints seeks leave of Court to reinstate his/her claims, for good cause shown, within fourteen (14) days of the filing of amended Consolidated Complaints. Lead Counsel shall file, concurrently with the amended Consolidated Complaints, a list of the allegations, claims, and/or defendant(s) to be dismissed without prejudice pursuant to this paragraph.

8. With respect to claims transferred to or filed in MDL 2543 after the filing of amended Consolidated Complaints, Lead Counsel shall have 60 days following transfer or filing to seek leave to amend the Consolidated Complaints, for good cause shown, to address any factual matter, claims and/or defendant(s) raised for the first time in such pleadings. If Lead Counsel do not seek leave to amend the Consolidated Complaints within the 60-day period, or if the requested amendment is denied by the Court, then any allegations, claims, and defendant(s) not included in the amended Consolidated Complaints shall be dismissed without prejudice at the expiration of the 60-day period or the Court's order denying the amendment, whichever occurs first, unless such plaintiff not named in the Consolidated Complaints sustains an objection to dismissal pursuant to the following procedure:

*16 a. On August 15, 2015, and every month thereafter (i.e., on the fifteenth day of every month) until the Court orders otherwise, Lead Counsel and Counsel for New GM shall jointly submit a list of allegations, claims, and defendant(s) in later-filed complaints to be dismissed without prejudice pursuant to this paragraph.

b. Any such plaintiff not named in the Consolidated Complaints may seek leave of Court to reinstate his/her claims, for good cause shown, within fourteen (14) days of the filing of the list naming his/her complaint to object to dismissal. Lead Counsel and New GM shall

have fourteen (14) days to respond. Any such objections and responses shall not exceed five (5) single-spaced pages and shall be filed in both 14-MD-2543 and 14-MC-2543. No replies shall be allowed without leave of Court.

9. The parties should meet and confer with an eye toward proposing an order to be entered after Plaintiffs file the amended Consolidated Complaints to ensure that motion practice and discovery with respect to common issues of fact and law are conducted as part of these MDL proceedings. Among other things, the proposed order should create a process requiring any Plaintiffs' counsel with allegations, claims, or defendants not included in the amended Consolidated Complaints to coordinate with Lead Counsel to ensure that discovery as to common issues of law and fact is completed as part of the MDL proceedings. Additionally, the parties should discuss whether, when, and how the Court should create a process to litigate the viability of allegations, claims, or defendants not included in the amended Consolidated Complaints.

10. For any allegations, claims, and defendants that have been or will be dismissed pursuant to Order No. 29 or this Order, the statute of limitations shall be tolled from the date of dismissal to 30 days after the Court decides Lead Counsel's motion for class certification.

Obligations of the Parties with Respect to Allegations, Claims, or Defendant(s) that are Reinstated Pursuant to the Preceding Paragraphs

11. If any allegations, claims or dismissed defendant(s) are reinstated after dismissal without prejudice pursuant to Order No. 29 or this Order, such individual economic loss plaintiff shall serve, in accordance with Order No. 30 (14-MD-2543 Docket No. 758), a plaintiff fact sheet ("PFS") within 30 days of this Order or of such reinstatement, whichever is later. Other than the obligation to serve a PFS, any individual economic loss action that is not dismissed pursuant to Order

No. 29 or this Order shall be stayed and no motion or responsive pleading to any allegations or claims or on behalf of a defendant reinstated by the Court shall be due unless and until ordered by the Court.

Procedure for Objecting to Application of Rulings on the Consolidated Complaints to Underlying Actions

12. In order to achieve the efficiencies of consolidation while respecting the principle that consolidation may not diminish the rights of plaintiffs, the Court adopts the following procedure to apply rulings made on the basis of consolidated pleadings to non-consolidated actions (*i.e.*, actions involving plaintiffs not named in the Consolidated Complaints). Rulings made with respect to the Consolidated Complaints shall apply to non-consolidated actions unless challenged as follows: Upon the application of any party to these MDL proceedings—to be made no later than fourteen (14) days following a Court ruling on the Consolidated Complaints—a party in a non-consolidated action shall be required to show cause within fourteen (14) days why a ruling made on the basis of the Consolidated Complaints should not apply to the non-consolidated action. The initial moving party shall then have seven (7) days to respond. Absent leave of Court, any such show cause papers and responses shall not exceed five (5) single-spaced pages and shall be filed in both 14-MD-2543 and 14-MC-2543. No replies shall be allowed without leave of Court.

*17 SO ORDERED.

Date: April 24, 2015

New York, New York

JESSE M. FURMAN United States District Judge

All Citations

Not Reported in F.Supp.3d, 2015 WL 3619584

TAB 29

309 Fed.Appx. 836

This case was not selected for publication in the Federal Reporter.

Not for Publication in West's Federal Reporter.

See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also Fifth Circuit Rules 28.7, 47.5.3, 47.5.4. (Find CTA5 Rule 28 and Find CTA5 Rule 47)

United States Court of Appeals,
Fifth Circuit.

In re: KATRINA CANAL BREACHES LITIGATION.

Maureen O'Dwyer et al., Plaintiffs-Appellants

v.

Board of Commissioners of the Port of New Orleans, Defendant-Appellee.

No. 08-30234.

|

Feb. 6, 2009.

Synopsis

Background: Property owner brought action against city port's board of commissioners, seeking to recover damages for levee breaches and flooding caused by hurricane. The United States District Court for the Eastern District of Louisiana, [Stanwood R. Duval Jr., J., 2007 WL 3003001](#), granted board's motion for judgment on the pleadings. Property owner appealed.

Holdings: The Court of Appeals held that:

[1] claims that appeared in property owner's individual complaint were superseded, and

[2] board was not responsible for design, construction, maintenance, or failure of levees and floodgates.

Affirmed.

Procedural Posture(s): On Appeal; Motion for Judgment on the Pleadings.

West Headnotes (3)

[1] **Federal Civil Procedure** Effect

Claims that appeared in property owner's individual complaint against city port's board of commissioners, seeking to recover damages for levee breaches and flooding caused by hurricane, but not in master consolidated class action complaint in litigation arising out of breaches and flooding, were superseded, where District Court entered a pre-trial order stating that the master complaint superseded and replaced all previously filed class action complaints. [Fed.Rules Civ.Proc.Rule 16\(e\), 28 U.S.C.A.](#)

5 Cases that cite this headnote

[2] **Water Law** Rights and liabilities in general

Water Law Breaches, flooding, and overflow

City port's board of commissioners was not responsible for design, construction, maintenance, or failure of levees and floodgates, and, thus, was not liable to property owner for damages resulting from levee breaches and flooding caused by hurricane, where Louisiana statute provided that levee district, not the board, had "full and exclusive right, jurisdiction, power, and authority to locate, relocate, construct, maintain, extend, and improve levees, embankments, seawalls, jetties, breakwaters, water-basins, and other works in relation to such projects." [LSA-R.S. 38:307.](#)

[3] **Federal Courts** Failure to mention or inadequacy of treatment of error in notice of appeal

Property owner failed to preserve for review on appeal claim that District Court and attorneys primarily responsible for producing master consolidated class action complaint in litigation arising out of levee breaches and flooding were improperly motivated by conflicts of interest and personal bias, where she did not include the claim

in her notice of appeal from District Court's order granting judgment on the pleadings in favor of city port's board of commissioners, in property owner's action seeking to recover damages for levee breaches and flooding caused by hurricane.

[3 Cases that cite this headnote](#)

Attorneys and Law Firms

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Appeal from the United States District Court for the Eastern District of Louisiana.

Before **GARWOOD, DENNIS, and PRADO**, Circuit Judges.

Opinion

PER CURIAM: *

* Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

**1 Plaintiffs–Appellants Maureen O'Dwyer et al. ("O'Dwyer") appeal the district court's grant of Rule 12(c) judgment on the pleadings in favor of Defendant–Appellee Board of Commissioners of the Port of New Orleans ("the Port"). O'Dwyer's appeal is without merit because it attempts to argue (1) an issue that was not raised or ruled upon below; and (2) an issue that relates to an alternative ground not essential to the district court's decision. Accordingly, we affirm the district court's judgment.

On August 17, 2006, O'Dwyer filed a class action lawsuit in the Eastern District of Louisiana seeking to recover damages for the levee breaches and flooding caused by Hurricane Katrina; the Port was among the many defendants named in this suit. O'Dwyer's suit was consolidated within the *In re: Katrina Canal Breaches Litigation* umbrella, and the claims at issue here were assigned to the "Levee" category.

On March 1, 2007, the district court issued Case Management Order No. 4 pursuant to [Federal Rule of Civil Procedure 16](#). This pre-trial order directed all class-action plaintiffs in the Levee category ("Levee Plaintiffs") to file a single Master Consolidated Class Action Complaint ("Master Complaint"). The order specifically stated that the Master Complaint "shall supersede and replace all previously filed class action complaints." The Levee *838 Plaintiffs complied with the order and filed a Master Complaint, which alleged that the Port held full responsibility and duty for the design, construction, and maintenance of certain levees in New Orleans and that the Port was therefore liable for any flood damage attributable to the failure of those levees.

O'Dwyer filed a "Notice of Objection" to the Master Complaint, asserting that the district court did not have the authority to supersede O'Dwyer's pleadings and objecting to the Master Complaint's use of the word "superseding." O'Dwyer offered no reasoning or authority in support of this objection.

The Port filed an answer to the Master Complaint on March 30, 2007, and subsequently moved for judgment on the pleadings, seeking to dismiss all the Master Complaint's claims against the Port for failure to state a claim upon which relief could be granted. No party opposed the Port's motion.

On October 12, 2007, [2007 WL 3003001](#), the district court issued an order and reasons granting the Port's motion for judgment on the pleadings. The district court noted that the motion was unopposed and granted the motion on the ground that the Port had no duties or responsibilities under Louisiana law with respect to levee maintenance or flood control; rather, the court held that [La.Rev.Stat. § 38:307](#) vested such duties and responsibilities exclusively in another state agency, the Orleans Levee District. No party filed a motion for reconsideration or a new trial in response to the district court's grant of the Port's motion for judgment on the pleadings, and on November 7, 2007, the Port filed a motion for entry of final judgment under Rule 54(b). Again, no party opposed the motion. Thus, on January 15, 2008, for the reasons stated in its order and reasons dated October 12, 2007, the district court entered judgment dismissing with prejudice the claims by O'Dwyer and others against the Port. O'Dwyer timely appealed, and we now affirm.

**2 [1] O'Dwyer argues that the district court erred in granting judgment on the pleadings because it failed to

consider the arguments presented in O'Dwyer's individual complaint but not presented in the Master Complaint. However, this argument lacks merit because the Master Complaint, filed pursuant to the district court's Rule 16 pre-trial order, superseded O'Dwyer's individual complaint. It is well settled that “[o]nce the pretrial order is entered, it controls the course and scope of the proceedings under **Federal Rule of Civil Procedure 16(e)**, and if a claim or issue is omitted from the order, it is waived, even if it appeared in the complaint.” *Elvis Presley Enters., Inc. v. Capece*, 141 F.3d 188, 206 (5th Cir.1998) (citing *Valley Ranch Dev. Co. v. FDIC*, 960 F.2d 550, 554 (5th Cir.1992); *Flannery v. Carroll*, 676 F.2d 126, 129–30 (5th Cir.1982)); *see also Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 474, 127 S.Ct. 1397, 167 L.Ed.2d 190 (2007) (“Here, we have not only an amended complaint, but a final pretrial order that superseded all prior pleadings and ‘controll[ed] the subsequent course of the action’ ”) (citing *Fed.R.Civ.P. 16(e)*; *Wilson v. Muckala*, 303 F.3d 1207, 1215 (10th Cir.2002) (“[C]laims, issues, defenses, or theories of damages not included in the pretrial order are waived even if they appeared in the complaint....”)). Here, the district court entered a **Rule 16** pre-trial order stating that the Master Complaint “shall supersede and replace all previously filed class action complaints.” Thus, O'Dwyer's individual complaint was superseded, and, contrary to O'Dwyer's assertions, any arguments or claims that appear in O'Dwyer's individual complaint but not in the Master Complaint were waived and cannot be considered on *839 appeal.¹ *See, e.g., Am. Rice, Inc. v. Producers Rice Mill, Inc.*, 518 F.3d 321, 335 (5th Cir.2008) (“If a claim or issue is omitted from the [pretrial] order, it is waived” (alteration in original)); *Arsement v. Spinnaker Exploration Co., LLC*, 400 F.3d 238, 245 (5th Cir.2005) (“It goes without saying that a pre-trial order controls the scope and course of trial; a claim or issue not included in the order is waived....”); *Elvis Presley Enters.*, 141 F.3d at 206.²

¹ Even if we were to consider the allegations in O'Dwyer's individual complaint, we would still find that the district court properly granted judgment on the pleadings because the allegations in O'Dwyer's individual complaint do not differ materially from those in the Master Complaint, which, as discussed *infra*, were properly dismissed in light of *La.Rev.Stat. § 38:307*.

² Alternatively, O'Dwyer contends that the district court should have allowed amendment of O'Dwyer's individual complaint before granting

the Port's motion for judgment on the pleadings. However, this argument again fails to understand that the Master Complaint, rather than O'Dwyer's individual complaint, was the relevant document for the district court to consider in evaluating whether judgment on the pleadings was proper. To the extent that O'Dwyer argues that the district court erred in not permitting amendment to the Master Complaint, such an argument is waived because neither O'Dwyer nor any other plaintiff filed before the district court a motion to amend the Master Complaint or a motion for reconsideration of the district court's judgment on the pleadings. *See Nichols v. Enterasys Networks, Inc.*, 495 F.3d 185, 189 (5th Cir.2007) (“As the issue has not been clearly raised in front of the district court, it cannot be considered on appeal.”); *FDIC v. Mijalis*, 15 F.3d 1314, 1327 (5th Cir.1994) (“[I]f a litigant desires to preserve an argument for appeal, the litigant must press and not merely intimate the argument during the proceedings before the district court. If an argument is not raised to such a degree that the district court has an opportunity to rule on it, we will not address it on appeal.”).

[2] We decline to address O'Dwyer's argument that the district court erred in alternatively basing its decision upon *La.Rev.Stat. § 9:2800(H)*. As an independent ground for granting the Port's motion, the district court relied on *La.Rev.Stat. § 38:307*, which gives the Orleans Levee District, not the Port, “full and exclusive right, jurisdiction, power, and authority to locate, relocate, construct, maintain, extend, and improve levees, embankments, seawalls, jetties, breakwaters, water-basins, and other works in relation to such projects.” *La.Rev.Stat. § 38:307* (emphasis added). Based on § 38:307, the district court concluded that the Levee Plaintiffs could prove no set of facts showing, as the Master Complaint alleged, that the Port was responsible and liable for the design, construction, maintenance, or failure of the levees and floodgates. We agree, and we hold that because the district court properly granted the Port's motion under § 38:307, any error in its alternative reliance on § 9:2800(H) would be harmless.

**3 [3] Finally, O'Dwyer argues that the district court and the attorneys primarily responsible for producing the Master Complaint were improperly motivated by conflicts of interest and personal bias. However, these issues are not properly presented in this appeal because O'Dwyer did not include them in her notice of appeal. Cf. *In re Katrina Canal*

Breaches Litig., —Fed.Appx. —, 2008 WL 5069808 at *1 (5th Cir.2008) (unpublished per curiam) (“O’Dwyer has filed, and the district court denied, two motions to recuse the district judge. Neither of the motions to recuse is part of this appeal.... We will not address issues that are not relevant to this appeal.”).

For these reasons, the judgment of the district court is AFFIRMED.

All Citations

309 Fed.Appx. 836, 2009 WL 290474

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TAB 30

 KeyCite Yellow Flag - Negative Treatment

Declined to Follow by [Le v. Kohls Department Stores, Inc.](#), E.D.Wis., February 8, 2016

2011 WL 5008090

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

In re MAGNESIUM OXIDE
ANTITRUST LITIGATION.

Civ. No. 10-5943 (DRD).

|
Oct. 20, 2011.

Attorneys and Law Firms

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OPINION

[DEBEVOISE](#), Senior District Judge.

*¹ This matter arises out of the consolidation of five separate actions in this Court¹ alleging a conspiracy to fix prices in and allocate shares of the domestic Magnesium Oxide

market from January 2002 to the present ("the Class Period"). On November 15, 2010, Direct Purchaser Plaintiffs ("DP Plaintiffs") Orangeburg Milling Company, Inc., Bar Ale, Inc., and Air Krete, Inc. filed a Class Action Complaint ("CAC") against Defendants Premier Chemicals, LLC ("Premier"), Sumitomo Corporation of America ("Sumitomo"), and YAS, Inc. ("YAS") pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, alleging violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, and seeking class certification under [Federal Rule of Civil Procedure 23\(b\)\(2\) and \(3\)](#), declaratory judgment, treble damages, costs and attorneys' fees, and an injunction. On December 30, 2010, DP Plaintiffs filed an Amended CAC to add additional factual allegations in support of their claims.

¹

See Docket Nos. 10-cv-5174, 10-cv-5352, 10-cv-6095, and 10-cv-6093, and 10-cv-5943, all of which were consolidated under Docket No. 10-cv-5943.

On October 7, 2010, Indirect Purchaser Plaintiffs ("IP Plaintiffs") Ronald Hayek, Daniel, Walker, Sue Walker, and John Bidart filed a CAC against Defendants under Section 16 of the Clayton Act, alleging violations of [Section 1](#) of the Sherman Act, and under various state antitrust and consumer protection laws. IP Plaintiffs seek similar relief as DP Plaintiffs.² On December 31, 2010, IP Plaintiffs filed an Amended CAC to add similar factual allegations as those added by DP Plaintiffs in their Amended CAC.

²

To be sure, IP Plaintiffs seek only injunctive relief for Defendants' alleged violations of federal antitrust laws, as only direct purchasers may bring federal antitrust actions for damages. *Illinois Brick v. Illinois*, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977).

On March 1, 2011, Defendants filed a Motion to Dismiss³ all of Plaintiffs' claims pursuant to [Federal Rule of Civil Procedure 12\(b\)\(6\)](#). For the reasons set forth below, Defendants' motion is granted. No Defendant is entitled to dismissal of Plaintiffs' federal and state antitrust claims on the merits because Plaintiffs sufficiently allege a meeting of the minds among all Defendants to fix prices in and allocate shares of the domestic Magnesium Oxide market. However, Defendants are entitled to dismissal of IP Plaintiffs' federal and state antitrust claims and the majority of their consumer protection claims for lack of standing. In addition, those consumer protection claims under which IP Plaintiffs

have standing are dismissed to the extent they are based on allegations of fraud because those allegations do not comply with the requirements of [Federal Rule of Civil Procedure 9\(b\)](#). Finally, Plaintiffs' federal and state antitrust claims are dismissed because they are time-barred by their respective statutes of limitations.

³ In fact, Sumitomo, Premier, and YAS each filed separate motions to dismiss. However, each joined in the others' arguments. Therefore, for the sake of simplicity and brevity, the Court will treat them as a single motion.

I. BACKGROUND

Magnesium Oxide ("MgO") is a solid, white, naturally occurring mineral that is used in producing a wide variety of products, including refractory products, animal feeds, fertilizers, electrical insulation, and pharmaceuticals. It is formed by an ionic bond between one magnesium atom and one oxygen atom. MgO can be mined from magnesite or processed from seawater or subterranean brines containing magnesium chloride. This case concerns the two most common forms of MgO: Caustic-calcined magnesia ("CCM") and dead-burned magnesia ("DBM"). DBM and CCM are produced differently and have different commercial applications.⁴

⁴ CCM "is manufactured at lower temperatures than [DBM] and is used in products like animal feeds and fertilizers." (Direct CAC ¶ 25; Indirect CAC ¶ 31.) DBM, on the other hand, "is most often used in refractory applications." (*Id.*)

*² In 2000, according to the CACs, domestic consumption of DBM and CCM came from two sources: the United States and China. Roughly 50% of CCM "and a lesser amount of" DBM consumed in the United States were produced domestically, while the rest was imported from China. (Direct Purchasers' Consolidated Amended Class Action Complaint ("Direct CAC") ¶ 27; (Indirect Purchasers' Consolidated Amended Class Action Complaint ("Indirect CAC") ¶ 33.) At that time, Premier allegedly maintained control over the majority of DBM and CCM consumed in the United States by (1) purchasing imported CCM and DBM for resale to its customers in the United States, and (2) sourcing magnesite from China for production into DBM to be sold domestically.

"Sumitomo similarly purchased Chinese MgO but only [DBM] for resale to its U.S. customers" and "sourced magnesite from China for manufacture into [DBM] for sale in the U.S." (Direct CAC ¶ 27; Indirect CAC ¶ 34.) To do so, it enlisted the help of YAS to (1) "facilitate[]its purchases of Chinese magnesite" (Direct CAC ¶ 27; Indirect CAC ¶ 35), and (2) purchase Chinese DBM for resale in the United States.

This arrangement proved successful because Hideo Sumikawa, the current president of YAS, previously worked for Sumitomo and has since maintained relationships with certain Chinese magnesite mines. "In particular, Sumitomo, through Coy Akiyama—head of Sumitomo's inorganic chemicals unit—purchases [DBM] from Chinese mines that Sumikawa (YAS) has facilitated, thereby allowing Sumitomo and YAS to participate together in the U.S. MgO market." (Direct CAC ¶ 33; Indirect CAC ¶ 41.)

According to Plaintiffs, sometime before the Class Period, Premier "saw its share of MgO markets shrink due to increased Chinese competition." (Direct CAC ¶ 28; Indirect CAC ¶ 36.) Specifically, "cheaper imports, mainly from China ha [d] replaced some of the U.S. domestic production, notably affecting Premier." (Direct CAC ¶ 29; Indirect CAC ¶ 37.) Thus, during the Class Period, Premier and Sumitomo allegedly bought nearly all of the Chinese DBM available for purchase and resold it to their customers in the United States.

In addition, Plaintiffs allege that, "[d]uring the Class Period, with some limited exceptions, the MgO markets were considered to be fairly saturated, with limited potential for growth." (Direct CAC ¶ 30; Indirect CAC ¶ 38.) However, "[i]nstead of competing, representatives from Premier, Sumitomo, and YAS began meeting regularly to discuss fixing U.S. MgO prices and allocating MgO markets." (Direct CAC ¶ 31; Indirect CAC ¶ 39.) Specifically, Plaintiffs allege a conspiracy among Premier, Sumitomo, and YAS to (1) fix prices in and allocate shares of the domestic DBM market and (2) allocate the domestic CCM market to Premier so that it could fix prices in that market, which resulted in Plaintiffs' purchasing DBM and CCM at artificially high prices.

i. The DBM and CCM Agreements

*³ Plaintiffs allege that, during the Class Period, Cary W. Ahl, Sr. Premier's then-president, "regularly called" Mr. Sumikawa of YAS "to discuss fixing Premier's and Sumitomo's [DBM] prices and allocating their respective MgO accounts in the U.S." (Direct CAC ¶ 34; Indirect CAC

¶42.) These market allocation and price-fixing schemes were allegedly implemented by Mr. Ahl and his successors at Premier and Terry Wakisama at Sumitomo.

In the summer of 2004, Coy Akiyama of Sumitomo, Mr. Sumikawa of YAS, Gary Vannorsdel, an animal nutrition broker, and Mr. Vannorsdel's son, met at a Holiday Inn, in Tulsa, Oklahoma, to discuss plans for Sumitomo to enter the CCM market without upsetting Premier. Sumitomo had been shipping DBM to the United States on "partially empty barges and wanted to maximize efficiencies by filling these barges with [CCM] for sale to the western U.S." (Direct CAC ¶ 39; Indirect CAC ¶ 48.) Indeed, DBM shipments filled only half of Sumitomo's New Orleans barge capacity. Apparently, "Tulsa was the only port that could accommodate this barge, and Sumitomo had access to a very large storage facility in Tulsa." (Direct CAC ¶ 36; Indirect CAC ¶ 44.)

At the Tulsa meeting, "[i]n the course of discussing a strategy for Sumitomo to enter the U.S. [CCM] market, Akiyama (Sumitomo) recounted to Sumikawa (YAS) multiple discussions between him and Ahl where Ahl had called Akiyama to set [DBM] prices; to allocate [DBM] markets; and to ensure that Sumitomo was maintaining its agreement with Premier to fix [DBM] prices and allocate [DBM] markets." (Direct CAC ¶ 40; Indirect CAC ¶ 49.) At one point, Mr. Vannorsdel "expressed concern about compromising his relationship with Premier by helping facilitate Sumitomo and YAS's involvement" in the CCM market, to which Mr. Akiyama responded, "'Don't be concerned because we [Sumitomo] talk with Premier on a daily basis to set prices and to discuss what accounts they can have.'" (Direct CAC ¶ 41; Indirect CAC ¶ 50.)

Shortly after the Tulsa meeting, Mr. Ahl discovered Sumitomo's plan to enter the CCM market and retaliated by dropping DBM prices.⁵ As a result, Sumitomo did not follow through with its plans to enter the CCM market. "Following the [CCM]-related message that Premier sent to Sumitomo and YAS via Premier's pre-market-entry retaliation, Sumitomo and YAS illegally agreed with Premier to remain out of the [CCM] market—a market Sumitomo, as a rational profit-seeking entity, was motivated to enter—thus allowing Premier to maintain its control over [CCM] pricing." (Direct CAC ¶ 43; Indirect CAC ¶ 52.)

⁵ These prices were later restored.

ii. Fraudulent Concealment

Plaintiffs allege that the MgO conspiracy was "inherently self-concealing" and that Defendants took affirmative measures to conceal it. (Direct CAC ¶ 48–49; Indirect CAC ¶ 55–56.) Specifically, Plaintiffs allege that "[D]efendants met secretly and among themselves for the express purpose of fixing prices and allocating markets of domestically sold MgO." (Direct CAC ¶ 50; Indirect CAC ¶ 57.) In addition, Defendants allegedly explained increases in the price of MgO "by references to tight supply, thinning margins, and increased energy and freight costs." (Direct CAC ¶ 51; Indirect CAC ¶ 58.) As a result, Plaintiffs allege that "neither [P]laintiffs nor the class members had knowledge of any of the foregoing violations, and neither [P]laintiffs nor the class members, until recently, could have discovered through reasonable diligence that [D]efendants and their co-conspirators had engaged in the foregoing violations." (Direct CAC ¶ 49; Indirect CAC ¶ 56.)

iii. The Complaints

*4 On November 15, 2010, DP Plaintiffs—i.e. those who purchased either DBM or CCM directly from one or more Defendants, their predecessors, subsidiaries, or co-conspirators during the Class Period—filed a CAC against Defendants under Sections 4 and 16 of the Clayton Act alleging violations of [Section 1](#) of the Sherman Act, and seeking class certification under [Federal Rule of Civil Procedure 23\(b\)\(2\) and \(3\)](#), declaratory judgment, treble damages, costs and attorneys' fees, and an injunction. On December 30, 2010, DP Plaintiffs filed an Amended CAC to add additional factual allegations in support of their claims.

On October 7, 2010, IP Plaintiffs—i.e. those who purchased products containing DBM or CCM that was manufactured, distributed or sold by one or more Defendants, their predecessors, subsidiaries, or co-conspirators during the Class Period—filed a CAC against Defendants under Section 16 of the Clayton Act, alleging violations of [Section 1](#) of the Sherman Act, and under various state antitrust and consumer protection laws, and seeking similar relief as the DP Plaintiffs. On December 31, 2010, IP Plaintiffs filed an Amended CAC to add similar factual allegations as those added by DP Plaintiffs in their Amended CAC.

II. DISCUSSION

Defendants now move to dismiss both Amended CACs pursuant to [Federal Rule of Civil Procedure 12\(b\)\(6\)](#). In

doing so, Defendants argue that Plaintiffs (1) lack standing to assert their federal and state antitrust claims; (2) fail to allege a plausible antitrust conspiracy to fix DBM prices, allocate portions of the domestic DBM market, and allocate the domestic CCM market to Premier; and (3) fail to plead fraudulent concealment with particularity to equitably toll the applicable federal and state antitrust statutes of limitations. Defendants further argue that IP Plaintiffs' lack standing to assert their consumer protection and unfair competition claims, and that those claims are improperly pled.

A. Standard of Review

In assessing the parties' arguments, the Court must apply the standard of review applicable to requests for dismissal pursuant to [Federal Rule of Civil Procedure 12\(b\)\(6\)](#). That rule permits a court to dismiss a complaint for failure to state a claim upon which relief can be granted. When considering a [Rule 12\(b\)\(6\)](#) motion, the Court must accept the factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir.1997). The Court's inquiry, however, "is not whether plaintiffs will ultimately prevail in a trial on the merits, but whether they should be afforded an opportunity to offer evidence in support of their claims." *In re Rockefeller Ctr. Prop., Inc.*, 311 F.3d 198, 215 (3d Cir.2002).

The Supreme Court recently clarified the [Rule 12\(b\)\(6\)](#) standard in two cases: *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009), and *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). The decisions in those cases abrogated the rule established in *Conley v. Gibson*, 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim, which would entitle him to relief." In contrast, *Bell Atlantic*, 550 U.S. at 545, held that "[f]actual allegations must be enough to raise a right to relief above the speculative level." Thus, the assertions in the complaint must be enough to "state a claim to relief that is plausible on its face," *id.* at 570, meaning that the facts alleged "allow [] the court to draw the reasonable inference that the defendant is liable for the conduct alleged." *Iqbal*, 129 S.Ct. at 1949; *see also, Phillips v. County of Allegheny*, 515 F.3d 224, 234–35 (3d Cir.2008) (In order to survive a motion to dismiss, the factual allegations in a complaint must "raise a reasonable expectation that discovery will reveal evidence of the necessary element," thereby justifying the

advancement of "the case beyond the pleadings to the next stage of litigation.").

*5 When assessing the sufficiency of a complaint, the Court must distinguish factual contentions—which allege behavior on the part of the defendant that, if true, would satisfy one or more elements of the claim asserted—from "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Iqbal*, 129 S.Ct. at 1949. Although for the purposes of a motion to dismiss the Court must assume the veracity of the facts asserted in the complaint, it is "not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* at 1950. Thus, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.*

When a claim is dismissed pursuant to [Federal Rule of Civil Procedure 12\(b\)\(6\)](#), leave to amend and reassert that claim is ordinarily granted. *In re Burlington Coat Factory Litig.*, 114 F.3d 1410, 1434 (3d Cir.1997). A claim may be dismissed with prejudice, however, if amending the complaint would be futile. *Id.* "Futile," as used in this context, means that the complaint could not be amended to state a legally-cognizable claim. *Id.* (citing *Glassman v. Computervision Corp.*, 90 F.3d 617, 623 (1st Cir.1996)).

B. Plaintiffs' Standing to Bring Antitrust Claims

Standing is a jurisdictional prerequisite under Article III of the United States Constitution. "Under Article III, the Federal Judiciary is vested with the 'Power' to resolve not questions and issues but 'Cases' or 'Controversies.'" "Arizona Christian Sch. Tuition Org. v. Winn, —U.S. —, —, 131 S.Ct. 1436, 1441, 179 L.Ed.2d 523 (2011). "To state a case or controversy under Article III, a plaintiff must establish standing." *Id.* at 1442 (citing *Allen v. Wright*, 468 U.S. 737, 751, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984)). The Supreme Court explained the elements of standing in *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992):

"First, the plaintiff must have suffered an 'injury in fact'—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) 'actual or imminent, not "conjectural" or "hypothetical." ' Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be 'fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not

before the court.’ Third, it must be ‘likely,’ as opposed to merely ‘speculative,’ that the injury will be ‘redressed by a favorable decision.’”

Defendants argue that Plaintiffs lack antitrust standing because they do not identify whether they purchased DBM or CCM. Specifically, Defendants contend that the alleged agreements regarding DBM and CCM, respectively, amount to “two conspiracies [that] are allegedly directed at different purchasers and encompass different time frames[,] and [n]othing indicates that anticompetitive activity in one market would have an effect on prices in the other market.” (YAS Br., 9.) “Under these circumstances,” according to Defendants, “a purchaser of [DBM] would suffer no redressable injury from anticompetitive conduct in the [CCM] market, and would accordingly lack standing to maintain claims based on such conduct (and vice versa).” (*Id.*).

*6 This argument is unavailing because, as discussed fully below, Plaintiffs allege a single conspiracy in the domestic MgO market comprised of two agreements: one to fix prices in and allocate shares of the domestic DBM market, and one to allocate the domestic CCM market to Premier. These agreements are interdependent in that Defendants entered into the CCM agreement in order to maintain the DBM agreement. As a result, price-fixing in the DBM market has an effect on prices in the CCM market, and vice versa, because the absence of one agreement would eliminate the consideration for the other.

As a general matter, DP Plaintiffs’ allegation that they were “injured by having paid more for MgO⁶ than they otherwise would have paid absent [D]efendants’ unlawful conduct” (Direct CAC ¶ 56) is sufficient to establish antitrust standing. Standing to sue under Section 4 of the Clayton Act is determined by a five-factor test:⁷ “(1) the causal connection between the antitrust violation and the harm to the plaintiff; (2) whether the plaintiff’s alleged injury is of the type that the antitrust laws were intended to redress; i.e., did the plaintiff suffer antitrust injuries; (3) the directness of the injury; (4) the existence of more direct victims of the violation; and (5) the potential for duplicative recovery or complex apportionment of damages.” *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 399 (3d Cir.2000) (citing *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 495 U.S. 519, 538 (1983)). Here, there is little doubt that those who purchased DBM and/or CCM directly from Defendants at supracompetitive prices have standing to sue for damages under Section 4 and for injunctive

relief under Section 16. See *id.* at 401 (“It is difficult to imagine a more formidable demonstration of antitrust injury” than supra-competitive pricing.); *In re Mercedes Benz Anti-Trust Litig.*, 157 F.Supp.2d 355, 364 (D.N.J.2001) (“Where, as here, it is alleged that consumers paid a price higher than the price that would have been offered had the dealers been competing, the purpose of the antitrust laws is obviously thwarted.”). Thus, DP Plaintiffs have standing to pursue their antitrust claims.

⁶ MgO collectively refers to DBM and/or CCM. (Direct CAC ¶ 1.)

⁷ As discussed further below, standing to assert claims for injunctive relief under Section 16 of the Clayton Act are analyzed under a more relaxed standard. See *In re Warfarin*, 214 F.3d at 399.

IP Plaintiffs, however, do not. While they seek solely injunctive relief under Section 16 of the Clayton Act—and therefore are not subject to the aforementioned five-factor test, *see Note 7*—they must still allege “(1) [a] threatened loss or injury cognizable in equity; (2) proximately resulting from the alleged antitrust injury.” *In re Warfin*, 214 F.3d at 400. In analyzing whether an antitrust injury proximately caused an alleged loss to an indirect purchaser, this Circuit has been guided by the Supreme Court’s decision in *Shield of Virginia v. McCready*, 457 U.S. 465, 102 S.Ct. 2540, 73 L.Ed.2d 149 (1982).⁸ *McCready* explained that “an antitrust violation may be expected to cause ripples of harm to flow through the Nation’s economy; but ... [i]t is reasonable to assume that Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action.” 457 U.S. at 476. Thus, in determining whether an injury was proximately caused by an antitrust violation for Article III standing purposes, courts should “look (1) to the physical and economic nexus between the alleged violation and the harm to the plaintiff, and (2) more particularly, to the relationship of the injury alleged with those forms of injury about which Congress was likely to have been concerned in making defendant’s conduct unlawful and in providing a private remedy.” *Id.* at 478. In doing so, they should consider whether the plaintiff’s injury is “inextricably intertwined with the injury that the conspirators sought to inflict,” *In re Warfarin*, 214 F.3d at 400–01 (purchasers of prescription drug whose active ingredient was the subject of a price-fixing conspiracy maintained standing to sue as indirect purchasers because “the excess amount paid” for the drug was “inextricably intertwined with the injury [Defendant] aimed to inflict”), or, put another way, “whether the injury

alleged is so integral an aspect of the conspiracy alleged, there can be no question but that the loss was precisely the type of loss that the claimed violations ... would be likely to cause.” *McCready*, 457 U.S. at 479 (quotations and citations omitted) (alleged conspiracy among psychiatrists and Blue Shield to take patients away from psychologists by refusing to reimburse Blue Shield subscribers for psychotherapeutic services resulted in “clearly foreseeable” harm to Blue Shield subscribers and “was a necessary step in effecting the ends of the alleged illegal conspiracy.”).

8 Although that decision analyzed proximate causation in the context of a Section 4 claim for damages, the Court of Appeals has applied its analysis to Section 16 claims because proximate cause is an element of standing under both. *See In re Warfin Sodium Antitrust Litig.*, 214 F.3d 395, 400–01 (3d Cir.2000).

*7 Here, IP Plaintiffs allege that “as a direct and proximate result of Defendants’ and their co-conspirators’ unlawful contract, combination and conspiracy, Plaintiffs and the Class members were injured and financially damaged in their business and property by having paid more for MgO Products than they would have absent Defendants’ and their coconspirators’ unlawful conduct.” (Indirect CAC ¶ 54.) However, they fail to specify which MgO products—i.e. products containing DBM or CCM—they purchased. The mere fact that a product contains DBM or CCM does not necessarily mean that an increase in the price of that product is “inextricably intertwined” with, or an “a necessary step in achieving the ends” of, the alleged conspiracy to fix prices in and allocate shares of the domestic DBM and CCM markets. Indeed, the price of DBM and CCM would have a minimal foreseeable effect on the price of products containing trace amounts of them, but a significant foreseeable effect on the price of products in which they are major ingredients. Thus, without knowing which specific products IP Plaintiffs purchased, it is impossible to determine whether an increase in their price is the type of injury that furthers the object of the alleged conspiracy to fix prices in and allocate shares of the domestic DBM and CCM markets. Accordingly, IP Plaintiffs’ federal antitrust claims are dismissed for lack of standing.⁹ However, IP Plaintiffs are granted leave to amend in order to allege (1) the specific purchased products containing DBM or CCM and (2) the nexus between an increase in the price of those products and the alleged conspiracy to fix prices in and allocate shares of the domestic DBM and CCM markets.

9 IP Plaintiffs also lack standing to assert their state antitrust claims because those claims are construed in accordance with federal antitrust principles. *See In re Digital Music Antitrust Litig.*, 592 F.Supp.2d 435, 448 n. 21 (S.D.N.Y.2008) (Arizona, California, District of Columbia, Iowa, Kansas, Maine, Michigan, Minnesota, North Carolina, South Dakota, Vermont, West Virginia, Wisconsin), *rev’d on other grounds by, Starr v. Sony BMG Music Entm’t.*, 592 F.3d 314 (2d Cir.2010); *T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass’n*, 809 F.2d 626, 635–36 (9th Cir.1987) (Hawaii); *Gutnayer v. Cendant Corp.*, 116 Fed. App’x 758, 761 (7th Cir.2004) (Illinois); *Monsanto Co. v. Swann*, No. 4:00–CV–1481, 2001 WL 34079480, at *3 (E.D.Mo. Sept.19, 2001) (Mississippi); *Neb.Rev.Stat. § 59–829 (2010)* (Nebraska); *Nev.Rev.Stat. § 598A.050 (2011)* (Nevada); *Minuteman, LLC v. Microsoft Corp.*., 147 N.H. 634, 637, 795 A.2d 833 (N.H.2002) (New Hampshire); *Clough v. Rush*, 959 F.2d 182, 187 (10th Cir.1982) (New Mexico); *Fido’s Fences v. Canine Fence Co.*, 672 F.Supp.2d 303, 313 (E.D.N.Y.2009) (New York); *Westgo Indus., Inc. v. W.J. King Co.*, Civil No. A3–75–82, 1981 WL 2064, at *6 (D.N.D. Mar.1, 1981) (North Dakota); *Oregon Laborers–Employees Health & Welfare Trust Fund v. Phili Morris, Inc.*, 185 F.3d 957, 963 n. 4 (9th Cir.1999) (Oregon); *In re Refalen Antitrust Litig.*, 221 F.R.D. 260, 278–79 (D.Mass.2004) (Tennessee); *Am. Airlines v. Christensen*, 967 F.2d 410, 414 (10th Cir.1992) (Utah).

Defendants further argue that IP Plaintiffs lack standing to assert their state law antitrust claims, with the exception of Iowa and California, because they only allege purchasing MgO products in Iowa and California. Specifically, Defendants contend that IP Plaintiffs “have no standing to bring claims based on violations of states in which they neither reside nor purchased any MgO products.” (Sumitomo Br. (IP Pl.), 4.) IP Plaintiffs counter that “Defendants improperly confuse ‘standing’ with class certification issues,” which, at this point, are premature. (IP Pl.’s Br., 30.) Specifically, IP Plaintiffs maintain that they “are not bringing claims in their own name in other states; rather they are seeking to represent similarly situated persons in other states,” and that “[t]his issue, improperly raised by Defendants on a motion to dismiss will be addressed at class certification under Rule 23.” (*Id.* at 31) (emphasis in original).

It is well-settled that a named plaintiff in a class action lawsuit is required to establish Article III standing. *See Lewis v. Casey*, 518 U.S. 343, 357, 116 S.Ct. 2174, 135 L.Ed.2d 606 (1996) (“That a suit may be a class action ... adds nothing to the question of standing, for even named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.” (quotations and citations omitted)); *Warth v. Seldin*, 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975) (“[T]he plaintiff still must allege a distinct and palpable injury to himself, even if it is an injury shared by a large class of other possible litigants.”); *O’Shea v. Littleton*, 414 U.S. 488, 494, 94 S.Ct. 669, 38 L.Ed.2d 674 (1974) (“[I]f none of the named plaintiffs purporting to represent a class establishes the requisite of a case or controversy with the defendants, none may seek relief on behalf of himself or any other member of the class.” (citations omitted)); *Winer Family Trust v. Queen*, 503 F.3d, 319, 326 (3d Cir.2007) (“The initial inquiry in either case is whether the lead plaintiff individually has standing.”).

*8 Less well-settled is whether, pre-class certification, named plaintiffs are required to establish standing for each and every claim set forth in a class action complaint, or whether it is sufficient to establish standing for a single claim because a court will determine if the named plaintiffs have standing to represent the unnamed class members seeking redress under the balance of asserted claims during the class certification process pursuant to **Federal Rule of Civil Procedure 23**. This issue typically arises in cases, such as this one, where named plaintiffs assert analogous causes of action under the laws of many states but cannot specifically tie their injuries to each state. Indeed, here, IP Plaintiffs, who allege that they purchased MgO products in Iowa and California, assert violations of twenty-five states' antitrust laws.¹⁰

¹⁰ At this time, IP Plaintiffs lack Article III standing to assert violations of the following state antitrust laws because they fail to allege a causal connection between their injuries and the conduct prohibited by the laws of those states, which require a showing that such conduct occurred, or whose effect was felt, in-state. *See A.R.S. § 44-1402* (Arizona) (“A contract, combination or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce, any part of which is within this state, is unlawful”); *DC ST § 28-4502* (District of

Columbia) (same); *HRS § 480-4* (Hawaii) (same); *10 M.R.S.A. § 1101* (Maine) (same); *SDCL § 37-1-3.1* (South Dakota) (same); *K.S.A. § 50-101* (Kansas) (“A trust is a combination of capital, skill, or acts, by two or more persons,” among other things, “[t]o fix any standard or figure, whereby such person's price to the public shall be, in any manner, controlled or established, any article or commodity of merchandise, produce or commerce intended for sale, use or consumption in this state”); *M.C.L.A. §§ 445.771, 445.772* (Michigan) (“A contract, combination, or conspiracy between 2 or more persons in restraint of, or to monopolize, trade or commerce in a relevant market is unlawful.... Relevant market means the geographical area of actual or potential competition in a line of trade or commerce, all or any part of which is within this state”); *M.S.A. § 325D.54* (Minnesota) (act applies to “(a) any contract, combination, or conspiracy when any part thereof was created, formed, or entered into in this state; and (b) any contract, combination, or conspiracy, wherever created, formed, or entered into; any establishment, maintenance, or use of monopoly power; and any attempt to establish, maintain, or use monopoly power; whenever any of the foregoing affects the trade or commerce of this state.”); *Neb. Rev. St. § 59-801* (Nebraska) (“Every contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce, within this state, is hereby declared to be illegal.”); *N.R.S. § 598A.060* (Nevada) (same); *N.M.S.A. § 1978, 57-1-1* (New Mexico) (same); *W.Va.Code § 47-18-3* (West Virginia) (same); *NY GBL § 340* (New York) (Every contract, agreement, arrangement or combination whereby ... [c]ompetition or the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state is or may be restrained ... is hereby declared to be against public policy, illegal and void.”); *N.C.G.S.A. § 75-1* (North Carolina) (“Every contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce in the State of North Carolina is hereby declared to be illegal.”); *NDCC, 51-08.1-01, 02* (North Dakota) (“A contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in a relevant market is unlawful.... Relevant market

means the geographical area of actual or potential competition in a line of commerce, all or any part of which is within this state.”); O.R.S. 646.705 (Oregon) (“As used in ORS 136.617 and 646.705 to 646.805, ‘trade or commerce’ means trade or commerce within the state; or between the state and any state, territory, or foreign nation.”); (Tennessee) **T.C.A. § 47-25-101** (“All arrangements, contracts, agreements, trusts, or combinations between persons or corporations made with a view to lessen, or which tend to lessen, full and free competition in the importation or sale of articles imported into this state, or in the manufacture or sale of articles of domestic growth or of domestic raw material, and all arrangements, contracts, agreements, trusts, or combinations between persons or corporations designed, or which tend, to advance, reduce, or control the price or the cost to the producer or the consumer of any such product or article, are declared to be against public policy, unlawful, and void.”). IP Plaintiffs’ allegations that “[P]rices for MgO and MgO Products were raised, fixed, maintained, and stabilized at artificially high levels throughout the states,” and “Defendants’ illegal conduct had a substantial effect on commerce in the above states” (Indirect CAC ¶¶ 72, 73) are conclusory and fail to specifically tie their injuries to the alleged MgO conspiracy occurring or its effects in those states.

IP Plaintiffs lack statutory standing to sue under Utah’s antitrust laws because they have a citizenship/residency requirement. *See* U.C.A. §§ 1953 **76-10-919** (“A person who is a citizen of this state or a resident of this state and who is injured or is threatened with injury in his business or property by a violation of the Utah Antitrust Act may bring an action for injunctive relief and damages, regardless of whether the person dealt directly or indirectly with the defendant.”), and under Illinois’s antitrust laws because they do not allow a private right of action. *See* **740 ILCS 10/7** (“This State, counties, municipalities, townships and any political subdivision organized under the authority of this State, and the United States, are considered a person having standing to bring an action under this subsection.”).

However, IP Plaintiffs apparently have standing to sue under Mississippi, New Hampshire, Vermont,

and Wisconsin antitrust laws, as they provide a private right of action and have no discernible requirement of in-state conduct or effect, or residency. *See* Miss.Code Ann. §§ 75-21-1, 9 (Mississippi); N.H. Rev. Stat § 356:1 (New Hampshire); **9 V.S.A. §§ 2453, 2465** (Vermont); **W.S.A. §§ 133.03, 133.18** (Wisconsin).

Courts, including this one, have held that “the fact that the named Plaintiffs may not have individual standing to allege violations of ... laws in states other than those in which they purchased Defendants’ [product] is immaterial [because] [t]he issue ... is one of predominance—whether questions of law or fact common to all class members predominate over any questions affecting only individual members.” *Ramirez v. STI Prepaid LLC*, 644 F.Supp.2d 496, 505 (D.N.J.2009) (quotations and citations omitted); *see also In re Grand Theft Auto Video Game Consumer Litig. (No. II)*, No. 06-MD-1739, 2006 WL 3039993, at *3 (S.D.N.Y. Oct. 25, 2006) (“The relevant question ... is not whether the Named Plaintiffs have standing to sue Defendants—they most certainly do—but whether their injuries are sufficiently similar to those of the purported Class to justify the prosecution of a nationwide class action. This question is, at least in the first instance, appropriately answered through the class certification process.”); *In re Buspirone Patent Litig.*, 185 F.Supp.2d 363, 377 (S.D.N.Y.2002) (“[T]hese alleged problems with standing will not arise unless class certification is granted. If certification is granted, the proposed class would contain plaintiffs who have personal standing to raise claims under the laws governing purchases in all of the [] states, and the only relevant question about the named plaintiffs’ standing to represent them will be whether the named plaintiffs meet the ordinary criteria for class standing ...”).

Other courts find that they must initially “review[] the standing of actual, not proposed plaintiffs” to assert the claims in a class action complaint because “[t]he alternative ... would allow named plaintiffs in a proposed class action, with no injuries in relation to the laws of certain states referenced in their complaint, to embark on lengthy class discovery with respect to injuries in potentially every state in the Union.” *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 154-56 (E.D.Pa.2009); *see also In re Potash Antitrust Litig.*, 667 F.Supp.2d 907, 924 (N.D.Ill.2009) (named plaintiffs are required to establish standing for each claim under which they purport to represent class members because “[t]o have standing as a class representative, the plaintiff must be part of the class, that is, he must possess the same interest and suffer the same injury shared by all members of the class he

represents.” (quotations and citations omitted)), *rev'd on other grounds by, Minn-Chem Inco. v. Agrium Inco.*, — F.3d —, No. 10-1712, 2011 WL 4424789 (7th Cir. Sept. 23, 2011); *In re Packaged Ice Antitrust Litig.*, 08-md-01952, 2011 WL 891160, at *11 (E.D.Mich. Mar. 11, 2011) (“[N]amed plaintiffs lack standing to assert claims under the laws of the states in which they do not reside or in which they suffered no injury.”).

*9 Two Supreme Court decisions, *Amchem Prods. Inc. v. Windsor*, 521 U.S. 591, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997) and *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 119 S.Ct. 2295, 144 L.Ed.2d 715 (1999), are at the heart of this issue. In *Amchem*, the Supreme Court reviewed a challenge to certification of a global settlement class involving persons who were exposed to asbestos. *See* 521 U.S. at 591–92. In doing so, it analyzed the role of settlement in determining class certification under Rule 23, as well as arguments set forth by objectors that certain members of the settlement class lacked standing to sue because they had not sustained a cognizable injury or because their injury was not redressable. *Id.* at 612. The Court declined to reach the standing arguments because it found the class certification issues under Rule 23 to be dispositive. *Id.* Consequently, the Court held that because resolution of the class certification issues “here is logically antecedent to the existence of Article III issues, it is appropriate to reach them first.” *Id.* (citation omitted).

The Court further explained that it was “follow[ing] the path taken by the [Third Circuit] Court of Appeals” in “declin[ing] to reach these issues because they ‘would not exist but for the [class-action] certification.’” *Id.* (quoting *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 623 (3d Cir.1996)). To be sure, in *Georgine*, the Court of Appeals, when faced with class certification and Article III issues simultaneously, decided the class certification issues first because they were dispositive. 83 F.3d at 623. In doing so, the Court found “it prudent not to decide issues unnecessary to the disposition of the case, especially when many of these issues implicate constitutional questions.” *Id.* (citing *Spector Motor Serv., Inc. v. McLaughlin*, 323 U.S. 101, 105, 65 S.Ct. 152, 89 L.Ed. 101 (1944) (expressing the rule that courts will avoid constitutional questions when possible)). Thus, these rulings echo the “fundamental and longstanding principle of judicial restraint [] requir[ing] that courts avoid reaching constitutional questions in advance of the necessity of deciding them.” *Lyng v. Northwest Indian Cemetery Protective Ass'n*, 485 U.S. 439, 445, 108 S.Ct. 1319, 99 L.Ed.2d 534 (1988).

The *Ortiz* court also dealt with certification issues regarding a global settlement class for asbestos related injuries and arguments regarding the Article III standing of certain class members who petitioners alleged did not suffer an injury-in-fact. 527 U.S. at 821, 831. As in *Amchem*, the Court decided to address the class certification issues before the Article III questions. *Id.* at 831. In doing so, it explained:

Ordinarily, of course, this or any other Article III court must be sure of its own jurisdiction before getting to the merits. *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 88–89, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998). But the class certification issues are, as they were in *Amchem*, “logically antecedent” to Article III concerns, 521 U.S., at 612, 117 S.Ct. 2231, 138 L.Ed.2d 689, and themselves pertain to statutory standing, which may properly be treated before Article III standing, *see Steel Co., supra*, at 92, 523 U.S. 83, 118 S.Ct. 1003, 140 L.Ed.2d 210. Thus the issue about Rule 23 certification should be treated first, “mindful that [the Rule's] requirements must be interpreted in keeping with Article III constraints....” *Amchem, supra*, at 612–613, 521 U.S. 591, 117 S.Ct. 2231, 138 L.Ed.2d 689.

*10 *Id.*

Thus, *Amchem* and *Ortiz* stand for the proposition that, in cases where a court is presented with class certification and Article III standing issues simultaneously, and the class certification issues are dispositive in that they pertain to statutory standing—i.e. whether a statute authorizes a given party to sue in the first place, the certification issues are “logically antecedent” to the standing issues and the court may therefore elect to address the certification issues first in the interest of judicial restraint. Under these circumstances, if a court finds that “certification of [a] proposed class [is] improper, the issue of certain class members' standing would [be] moot.” *In re Welbutrin XL*, 260 F.R.D. at 153.

Here, however, the Court is presented solely with the issue of whether the named IP Plaintiffs have standing to assert the causes of action in the Indirect CAC, a threshold issue that the Court must address. *See Lewis* 518 U.S. at 357. Contrary to *Ramirez* and *In re Grand Theft Auto*, the “[Supreme] Court's standing cases confirm that a plaintiff must demonstrate standing for each claim he seeks to press.” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 335, 126 S.Ct. 1854, 164 L.Ed.2d 589 (2006); *see also Allen v. Wright*, 468 U.S. 737, 752, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984) (“[T]he

standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted."); *Blum v. Yaretsky*, 457 U.S. 991, 999, 102 S.Ct. 2777, 73 L.Ed.2d 534 (1982) ("It is not enough that the conduct of which the plaintiff complains will injure *someone*. The complaining party must also show that he is within the class of persons who will be concretely affected. Nor does a plaintiff who has been subject to injurious conduct of one kind possess by virtue of that injury the necessary stake in litigating conduct of another kind, although similar, to which he has not been subject."). Otherwise, a plaintiff would be able to bring a class action complaint under the laws of nearly every state in the Union without having to allege concrete, particularized injuries relating to those states, thereby dragging defendants into expensive nationwide class discovery, potentially without a good-faith basis. In other words, the plaintiff would have to do "no more than name the preserve on which he intends to hunt." *Johnson v. Ga. Highway Express, Inc.*, 417 F.2d 1122, (5th Cir.1969), overruled on other grounds by *Griffin v. Dugger*, 823 F.2d 1476 (11th Cir.1987). Accordingly, because the named IP Plaintiff lack standing to assert antitrust violations under the laws of Arizona, the District of Columbia, Hawaii, Illinois, Maine, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, and West Virginia, *see* Note 10, IP Plaintiffs' claims under those laws are dismissed.

C. The Alleged MgO Conspiracy

i. One Conspiracy or Two

*11 As an initial matter, Defendants maintain that Plaintiffs' allegations are confusing to the point where it is impossible to determine whether the alleged conspiracy relates to DBM, CCM, or MgO in general. As a result, Defendants contend that Plaintiffs fail to allege a plausible antitrust conspiracy. This contention is unfounded. While Plaintiffs at times refer to anticompetitive conduct regarding MgO generally, it is clear from the surrounding allegations whether such conduct concerns DBM or CCM.¹¹ Indeed, as evidenced by their next contention, Defendants have no problem categorizing Plaintiffs' individual allegations as relevant to DBM or CCM.

¹¹ Moreover, the CACs specifically note at the outset that the term MgO can refer to DBM or CCM. *See* (Direct CAC ¶ 1; Indirect CAC ¶ 1 n. 1).

On that note, Defendants contend that, to the extent that the Court finds that Plaintiffs allege distinct conspiracies regarding DBM and CCM, respectively, the Court should analyze the allegations relating to each conspiracy separately and require that those allegations independently meet the pleading requirements of *Twombly* and *Iqbal*. Plaintiffs counter that they allege a single MgO conspiracy comprised of intertwined and interdependent anticompetitive agreements.

As Plaintiffs point out, it is well-settled that "[t]he character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole." *Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699, 82 S.Ct. 1404, 8 L.Ed.2d 777 (1962); *see also In re Fine Paper Antitrust Litig.*, 685 F.2d 810, 822 (3d Cir.1982) ("a seriatim examination of [] claims against each [] conspiracy defendant[] as if they were separate lawsuits ... overlook[s] the conspiracy itself."). Defendants contend that the Supreme Court's ruling in *Continental Ore* is inapposite because that case concerned a monopolistic exclusion conspiracy, as opposed to a price-fixing conspiracy. This contention is remarkably unpersuasive. The very case that *Continental Ore* cites for the proposition that a court must look to an alleged conspiracy as a whole, *United States v. Patten*, 226 U.S. 525, 33 S.Ct. 141, 57 L.Ed. 333 (1913), concerned a conspiracy to artificially inflate the price of cotton. Furthermore, there is no indication that *Continental Ore* limited its ruling to conspiracies based on monopolistic exclusion. *See* 370 U.S. at 699 ("we do not believe that ... liability under the antitrust laws can be measured by any rigid or mechanical formula ..."). Finally, Defendants fail to present, nor does the Court see, a single reason why it would be any less logical or equitable to assess an alleged price-fixing or market allocation conspiracy as a whole than a monopolistic exclusion conspiracy.

Defendants' contention that the Court should analyze Plaintiffs' allegations separately with respect to DBM and CCM because Plaintiffs allege "two different courses of conduct as to the two different products at two different times" (Sumitomo Reply Br., 3) is also unavailing. While it is true that Defendants initially "agreed to fix prices and allocate markets for DBM," ("the DBM Agreement") and subsequently agreed to allocate the domestic CCM market to Premier ("the CCM Agreement"), (*id.*), those agreements are not mutually exclusive. To the contrary, the CCM Agreement is dependent on the DBM Agreement,

and vice versa. See *In re Vitamins Antitrust Litig.*, 320 F.Supp.2d 1, 16 (D.D.C.2004) (recognizing the potential “interdependency between various branches of a common conspiracy.”). Specifically, Defendants entered into the CCM Agreement in order to restore and maintain the DBM Agreement after Premier broke that agreement due to Sumitomo and YAS's attempt to enter the domestic CCM market. Consequently, the absence of one eliminates the consideration for the other. Moreover, “[h]orizontal antitrust conspiracies commonly include sellers in more than one relevant market.” *In re Vitamins Antitrust Litig.*, No. MISC 99-197, 2000 WL 1475705, at *10 (D.D.C. May 9, 2000). Accordingly, the Court will treat Plaintiffs CACs as alleging a single conspiracy not to compete in the sale of two forms of MgO.

ii. The Necessity of Allegations Regarding the MgO Market

*12 Defendants argue that Plaintiffs fail to allege an unlawful price-fixing and market allocation conspiracy because they do not set forth relevant market conditions and Sumitomo's, YAS's, and Premier's relative market power indicating that they plausibly could have fixed the price of DBM and allocated the domestic DBM and CCM markets. Plaintiffs argue that they are alleging per se violations of Section 1 of the Sherman Act and therefore “Defendants' arguments concerning market power and relevant markets are legally irrelevant.” (DP Pl's. Br., 12.)

“Section 1 of the Sherman Act provides: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 314 (3d Cir.2010) (quoting 15 U.S.C. § 1). “[T]his statutory language imposes two essential requirements on an antitrust plaintiff.” *Id.* “First, the plaintiff must show that the defendant was a party to a contract, combination ... or conspiracy.” *Id.* at 315 (quotation and citation omitted). This requires the plaintiff to demonstrate “some form of concerted action” indicating a “unity of purpose or a common design and understanding or a meeting of the minds or a conscious commitment to a common scheme.” *Id.* (quotations and citations omitted).

Second, “the plaintiff must show that the conspiracy to which the defendant was a party imposed an unreasonable restraint on trade.” *Id.* (quotation and citation omitted). “[T]he usual standard applied to determine whether a challenged practice unreasonably restrains trade is the so-called rule of reason.”

Id. (quotation and citation omitted). “[U]nder a rule-of-reason analysis, the plaintiff bears the initial burden of showing that the alleged [agreement] produced an adverse, anticompetitive effect within the relevant geographic market.” *Id.* (quotation and citation omitted). “[S]uccessful attempts to meet this burden typically include a demonstration of defendants' market power, as a judgment about market power is [a] means by which the effects of the [challenged] conduct on the market place can be assessed.” *Id.* at 315–16 (quotation and citations omitted).

“If the plaintiff carries this burden, the court will need to decide whether the anticompetitive effects of the practice are justified by any countervailing pro-competitive benefits.” *Id.* However, “Judicial experience has shown that some classes of restraints” almost never have “redeeming competitive benefits,” and therefore a court need not apply the rule of reason analysis. *Id.* Instead, they are “subject to a ‘per se’ standard.” *Id.* “Paradigmatic examples are horizontal agreements among competitors to fix prices or to divide markets.” *Id.* (quotation and citation omitted). If a plaintiff's allegations “fall into one of the recognized classes,” an unreasonable restraint on trade is “conclusively presumed” and therefore “plaintiffs are relieved of the obligation to define a market and prove market power.” *Id.* (citations omitted).

*13 As discussed below, Plaintiffs sufficiently allege that Defendants entered into (1) a horizontal agreement to fix prices in and allocate shares of the domestic DBM market and (2) a horizontal agreement to allocate the domestic CCM market to Premier. Accordingly, Plaintiffs assert per se antitrust violations that do not require allegations regarding the nature of the domestic DBM and CCM markets or Defendants' power within those markets.¹²

¹² This also disposes of Sumitomo's contention that the Court should consider “certain relevant facts” noted in *Animal Science Prods., Inc. v. China Nat'l Metals & Minerals*, 596 F.Supp.2d 842 (D.N.J.2008) regarding the domestic DBM and CCM markets. (Sumitomo (DP Pl.'s) Br., 4.)

iii. The DBM Agreement

Defendants argue that Plaintiffs' allegations of an agreement to fix prices in and allocate shares of the domestic DBM market are facially insufficient because (1) they fail to provide the substance of the agreement, (2) they fail to rule out potentially alternative, lawful explanations for such

an agreement, and (3) their “factual narrative is inherently implausible.” (Sumitomo (DP Pl’s.) Br., 15.) Plaintiffs argue that their allegations of a price-fixing and market allocation agreement are sufficient because (1) they “explicitly state who was conferring with whom about MgO pricing, markets and customers” (DP Pl’s. Br., 15.), and (2) Defendants’ arguments regarding the inherent plausibility of the alleged conspiracy implicate factual questions that are not properly resolved on a motion to dismiss.

Defendants’ contention that Plaintiffs’ allegations are inadequate because they “fail to disclose the actual substance of the alleged conversations or agreements” (Sumitomo (DP Pl’s.) Br., 14) is unavailing. *Twombly* does not require detailed allegations regarding the specific nature of a price-fixing or market allocation agreement; rather, “stating such a claim requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made.” *550 U.S. at 556*. Put another way, a complaint “simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of an illegal agreement.” *Id.* Requiring Plaintiffs to set forth the full details of an antitrust conspiracy at this stage of the litigation would present an onerous burden because “in antitrust cases, [] the proof is largely in the hands of the alleged conspirators.” *In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *7 (D.N.J. Aug.28, 2009) (quoting *Hosp. Building Co. Trustees of Rex Hosp.*, 425 U.S. 738, 96 S.Ct. 1848, 48 L.Ed.2d 338 (1976)).

Here, Plaintiffs allege that (1) a significant portion of DBM consumed in the United States comes from China; (2) during the Class Period, Premier and Sumitomo bought nearly all Chinese DBM available for purchase and resold it to their customers in the United States; (3) Mr. Ahl of Premier “regularly called” Mr. Sumikawa of YAS “to discuss fixing Premier’s and Sumitomo’s [DBM] prices and allocating their respective MgO accounts in the U.S” (Direct CAC ¶ 34; Indirect CAC ¶ 42); (4) these market allocation and price-fixing schemes were implemented by Mr. Ahl and his successors at Premier and Mr. Wakisama of Sumitomo; (5) at the 2004 Tulsa meeting, Mr. Akiyama recounted to Mr. Sumikawa “multiple discussions” between him and Mr. Ahl to set DBM prices and allocate DBM markets “and ensure that Sumitomo was maintaining its agreement with Premier to fix [DBM] prices and allocate [DBM] markets,” (Direct CAC ¶ 40; Indirect CAC ¶ 49); and (5) when Mr. Vannorsdel allegedly “expressed concern about compromising his relationship with Premier by helping facilitate Sumitomo and YAS’s involvement” in the CCM

market, Mr. Akiyama responded, “ ‘Don’t be concerned because we [Sumitomo] talk with Premier on a daily basis to set prices and to discuss what accounts they can have.’ ” (Direct CAC ¶ 41; Indirect CAC ¶ 50.)

*14 These allegations plausibly suggest that Defendants entered into an agreement to fix prices in and allocate shares of the domestic DBM market, the specifics of which can be reasonably expected to be revealed in discovery. Plaintiffs state (1) the subject of the alleged agreement, (2) the parties to the agreement and the specific individuals that discussed and implemented the agreement, and (3) the context in which the agreement arose. This is sufficient to withstand a motion to dismiss.

Defendants’ contention that Plaintiffs fail to assert a plausible antitrust conspiracy because their allegations could, in fact, refer to a lawful vertical agreement between Sumitomo and Premier to fix prices for DBM whereby Sumitomo purchases DBM from Premier as a reseller, is irrelevant. At the pleading stage, Plaintiffs need only set forth allegations that create an inference of an unlawful agreement, *Twombly*, *550 U.S. at 556*, which, as previously discussed, they have done; they need not set forth allegations tending to rule out potential alternative explanations.¹³

13 This is to be distinguished from the requirement to plead plus factors to rule out independent action “when a plaintiffs’ claims of conspiracy rest on parallel conduct,” *In re Ins. Brokerage*, 618 F.3d at 323, which is discussed below regarding the alleged CCM Agreement. Plaintiffs need not assert plus factors to establish the plausibility of the DBM Agreement because they set forth direct allegations of that agreement. See *In re Ins. Brokerage*, 618 F.3d at 323 (“Allegations of direct evidence of an agreement, if sufficiently detailed, are independently adequate.”).

Finally, Defendants’ contention that the alleged DBM Agreement is “inherently implausible” in that, on the one hand, Sumitomo was allegedly worried about retaliatory action by Premier for attempting to enter the CCM market and, on the other hand, “could give credible assurances to the Vannorsdels that it could shield them from Premier’s retaliation because of [Sumitomo’s] ‘daily’ contact with Premier,” (Sumitomo (DP Pl’s.) Br., 15) is similarly irrelevant because it asks the Court to improperly assess the merits of Plaintiffs’ allegations.¹⁴ See *Aktieselskabet AF* 21. November

2001 v. Fame Jeans Inc., 525 F.3d 8, 17 (D.C.Cir.2008) (“*Twombly* was concerned with the plausibility of an inference of conspiracy, not with the plausibility of a claim. A court deciding a motion to dismiss must not make any judgment about the probability of the plaintiff's success ... the court must assume that all the allegations in the complaint as true (even if doubtful in fact)” (quotations and citations omitted)). Thus, Plaintiffs have sufficiently alleged an unlawful agreement among Defendants to fix prices in and allocate shares of the domestic DBM market.

14 Moreover, there is nothing “inherently implausible” about Sumitomo's attempt to assuage the Vannorsdels' concern about Premier's potential retaliation by stating that it speaks with Premier on a daily basis to set DBM prices and allocate shares of the DBM market. It is certainly plausible that Sumitomo was aware of the risk of retaliation by Premier but believed it could “enter the [CCM] market discreetly” (Direct CAC ¶ 39; Indirect CAC ¶ 48) because Premier's attention was focused on maintaining their agreement in the DBM market.

iv. The CCM Agreement

Defendants contend that Plaintiffs fail to allege the existence of an unlawful agreement to allocate the domestic CCM market to Premier because (1) they merely allege parallel conduct that does not indicate concerted action, (2) there are obvious alternative explanations for Sumitomo's and YAS's decision not to enter the CCM market, and (3) they fail to establish that Defendants were competitors in the CCM market. Plaintiffs counter that they are not relying on parallel conduct but rather direct admissions of an agreement among Defendants to allocate the domestic CCM market to Premier, and therefore Defendants' proffered alternative explanations are irrelevant.

As previously discussed, *Section 1* of the Sherman Act “does not prohibit [all] unreasonable restraints of trade ... but only restraints effected by a contract, combination, or conspiracy.” *Twombly*, 550 U.S. at 553 (quotation and citation omitted). This is because seemingly anticompetitive conduct may be just as “consistent with conspiracy ... [as] with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market.” *Id.* at 554 (citation omitted). Accordingly, “[t]he crucial question is whether the challenged anticompetitive conduct stem[s] from independent decision or from an agreement, tacit or express.” *Id.* at 553 (quotation and citation omitted). “Hence,

when allegations of parallel conduct are set out in order to make a § 1 claim, they must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action.” *Id.* at 557.

*15 This is usually accomplished by pleading one or more “plus factors” that “indicate the existence of an actionable agreement.” *In re Ins. Brokerage*, 618 F.3d at 321. While “[t]here is no finite set of such criteria,” the Court of Appeals has identified “at least three such plus factors: (1) evidence that the defendant had a motive to enter into a[] conspiracy; (2) evidence that the defendant acted contrary to its interests; and (3) evidence implying a traditional conspiracy.” *Id.* at 321–22 (quotations and citation omitted).

Here, Plaintiffs' allegations suggest an agreement among Defendants to allocate the CCM market to Premier. Plaintiffs allege that (1) representatives from Sumitomo and YAS met with others at a Tulsa hotel, in the summer of 2004, to discuss entering the domestic CCM market in order to fill Sumitomo's barge capacity; (2) Premier discovered their plan to enter the domestic CCM market and retaliated by lowering DBM prices; and (3) as a result, Sumitomo and YAS agreed with Premier to remain out of the CCM market.

To be sure, contrary to Plaintiffs' contentions, these allegations do not amount to a direct admission of an unlawful agreement to allocate the CCM market to Premier; taken in isolation, they merely amount to parallel conduct plus a conclusory allegation of an agreement. Placing these allegations in the context of the CACs as a whole, however, Plaintiffs successfully demonstrate the first plus factor—that Sumitomo and YAS had a motive to enter into an unlawful agreement with Premier to stay out of the domestic CCM market—and provide a plausible context for that agreement. As previously discussed, Sumitomo and YAS maintained an agreement with Premier to fix prices in and allocate shares of the domestic DBM market. As a result, as the CACs indicate, Sumitomo and YAS wanted to enter the CCM market undetected so that they could continue to maintain their agreement with Premier in the DBM market. When Premier discovered their plans and, in response, cut prices in the DBM market, Sumitomo and YAS agreed with Premier to stay out of the CCM market with the motive of restoring and maintaining their agreement in the DBM market.

In this context, Defendants' alternative explanations that a profit-maximizing entity could independently decide not to

enter a market in which (1) it remained unfamiliar with the product and its customers and (2) the dominant player recently cut prices are by no means “obvious” or “more plausible” (Sumitomo (DP Pl's.) Br., 18) than an illegal agreement to stay out of the CCM market and therefore do not provide a basis for dismissal. At the pleading stage, “a claim of conspiracy predicated on parallel conduct should be dismissed if common economic experience, or the facts alleged in the complaint itself, show that independent self-interest is an obvious alternative explanation for defendants' common behavior.” *In re Ins. Brokerage*, 618 F.3d at 326. Plaintiffs' allegations need not rule out all potential alternative explanations. *See Starr v. Sony BMG Music Entertainment*, 592 F.3d 314, 352 (2d Cir.2010) (“Although the *Twombly* court acknowledged that for purposes of summary judgment a plaintiff must present evidence that tends to exclude the possibility of independent action, it specifically held that, to survive a motion to dismiss, plaintiffs need only enough factual matter (taken as true) to suggest that an agreement was made” (quotations and citations omitted)).

*16 Finally, Sumitomo's argument that Plaintiffs fail to allege a plausible agreement to allocate the CCM market to Premier because there is no indication that Defendants were actual or potential competitors in the CCM market is unavailing. Sumitomo specifically contends that Plaintiffs must establish that it had the intent and capability of entering the CCM market as a competitor in order to allege a plausible agreement among Defendants to allocate the CCM market to Premier. However, the authority cited by Sumitomo provides little support for this contention. *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49–50, 111 S.Ct. 401, 112 L.Ed.2d 349 (1990) (parties need not have competed in the same territorial market to unlawfully allocate that market); *Andrx Pharm, Inc. v. Bioval Corp., Int'l*, 256 F.3d 799, 806–07 (D.C.Cir.2001) (potential competitor must show background and experience in new market, financial capability to enter market, and affirmative steps toward entry in order to establish injury-in-fact for standing to sue under Section 4 of the Clayton Act); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 9 (1st Cir.1979) (to sustain jury finding of unlawful horizontal market allocation agreement among potential competitors, there must have been sufficient support in the record to establish that potential competitors had the “necessary desire, intent, and capability to enter the market”).

To be sure, the Court of Appeals has generally recognized that the existence of an unlawful horizontal agreement to allocate

a given market must occur among competitors or potential competitors in that market:

An agreement among persons who are not actual or potential competitors in a relevant market is for Sherman Act purposes *brutum fulmen* ... To some extent, of course, a horizontal agreement tends to define the relevant market, for it tends to show that the parties to it are at least potential competitors. If they were not, there would be no point to such an agreement. Thus its very existence supports an inference that it would have an effect in a relevant market. Where, ... however, the disputed issue is the existence or scope of the alleged horizontal agreement that is to be inferred from circumstantial evidence, the first inquiry must be whether or not each firm alleged to have been a party to it was an actual or potential competitor in that market.

United States v. Sargent Elec. Co., 785 F.2d 1123, 1127 (3d Cir.1986) (reversing dismissal of indictment on double jeopardy grounds). However, Sumitomo fails to present, nor is the Court aware of, any authority requiring a purchaser plaintiff to specifically establish, at the pleading stage, that the parties to a horizontal agreement to allocate a given market were competitors or potential competitors in that market. To require Plaintiffs, pre-discovery, to establish Sumitomo's background and experience in the CCM market, its financial capability to enter that market, and the specific steps taken by Sumitomo to enter it, would be overly onerous, as much of this information is likely to be exclusively in the hands of Sumitomo.¹⁵ Thus, Plaintiffs have sufficiently alleged an unlawful agreement among Defendants to allocate the domestic CCM market to Premier.

¹⁵ In any event, Plaintiffs allege Sumitomo's motive for entering the CCM market (filling excess barge capacity), and certain steps taken to enter that market (meeting with the Vannorsdels in Tulsa).

v. YAS' Involvement in the Alleged Conspiracy

*17 YAS separately argues that Plaintiffs fail to establish its participation in the alleged conspiracy because they fail to show that it came to a meeting of the minds with Sumitomo and Premier to (1) fix prices in and allocate shares of the domestic DBM market and (2) allocate the CCM market to Premier.¹⁶ Plaintiffs counter that (1) they have set forth direct allegations indicating YAS's knowledge and participation in the alleged conspiracy, and (2) YAS need not have played the same role in the conspiracy, maintain the same motives as Sumitomo or Premier for participating in it, or sell MgO to be held liable.

¹⁶ Citing to *Toledo Mack Sales & Serv. v. Mack Trucks, Inc.*, 530, F.3d 204 (3d Cir.2008), YAS further argues that Plaintiffs' failure to establish that YAS occupies the same level as Sumitomo and Premier on the MgO supply chain "precludes *per se* treatment of YAS' alleged antitrust violations." (YAS Br., 4 n. 5.) This argument misses the mark. While *Toledo Mack* noted that, "[i]n contrast to horizontal price-fixing agreements between entities at the same level of a product's distribution chain, the legality of a vertical agreement that imposes a restriction on the dealer's ability to sell the manufacturer's product is governed by the rule of reason," and that "[t]he rule of reason analysis applies even when ... the plaintiff alleges that the purpose of the vertical agreement between a manufacturer and its dealers is to support illegal horizontal agreements between multiple dealers," 530 F.3d at 225 (citation omitted), Plaintiffs do not allege YAS' arrangement with Sumitomo to source Chinese magnesite and MgO constitutes an unlawful vertical agreement to support a horizontal conspiracy between Sumitomo and Premier. Rather, Plaintiffs allege that YAS participated directly with Sumitomo and Premier in the alleged horizontal conspiracy to fix prices in and allocate shares of the DBM market and allocate the CCM market to Premier. Moreover, "[t]he law is settled that where an upstream supplier participates in a conspiracy involving horizontal competitors, it is proper to analyze the entire restraint as one of horizontal price-fixing." *In re Mercedes-Benz*, 157 F.Supp.2d at 362.

As previously discussed, to hold YAS or any other Defendant liable, Plaintiffs must set forth allegations suggesting that

YAS maintained "unity of purpose or a common design and understanding or a meeting of minds or a conscious commitment to a common scheme" with Sumitomo and Premier to (1) fix prices in and allocate shares of the domestic DBM market, and (2) allocate the CCM market to Premier. *In re Ins. Brokerage*, 618 F.3d at 315 (quotations and citation omitted). This does not require a showing that YAS knew of or participated in every transaction in furtherance of or related to the alleged conspiracy. See *TV Signal Co. of Aberdeen v. American Tel. & Tel. Co.*, 462 F.2d 1256, 1259 (8th Cir.1972) ("Although knowledge is implicit in the requirement of unity of purpose, no case of which we are aware requires that each party to a conspiracy knows of each transaction encompassed by the conspiracy in order to be held accountable therefore."); *In re Vitamins Antitrust Litig.*, 320 F.Supp.2d 1, 15 (D.D.C.2004) ("Although Plaintiffs must show that each Defendant had knowledge of an agreement as to the overall conspiracy, they need not show (1) evidence of a formal agreement, or (2) knowledge, on behalf of the Defendant, of every detail of the alleged conspiracy."); *In re Mercedes-Benz*, 157 F.Supp.2d at 375 ("That a particular defendant may or may not have joined in a specific overt act in furtherance of the conspiracy ... does not affect its status as a conspirator."). On the other hand, "knowledge alone [of the conspiracy] is not sufficient" to hold it liable. *In re Vitamins*, 320 F.Supp.2d at 16. Plaintiffs must therefore set forth allegations suggesting that YAS (1) had knowledge of the conspiracy to fix prices in and allocate shares of the domestic DBM market, and allocate the CCM market to Premier, and (2) intended to join that conspiracy. *Id.* "[A] party progresses from mere knowledge of an endeavor to intent to join it when there is 'informed and interested cooperation, stimulation, instigation. And there is also a stake in the venture which, even if it may not be essential, is not irrelevant to the question of conspiracy.' " *Id.* (quoting *Direct Sales Co. v. United States*, 319 U.S. 703, 713, 63 S.Ct. 1265, 87 L.Ed. 1674 (1943)).

1. The DBM Agreement

Plaintiffs allege that Mr. Sumikawa of YAS (1) facilitates Sumitomo's purchases of Chinese DBM for resale in the domestic DBM market, (2) received regular phone calls from Mr. Ahl of Premier "to discuss fixing Premier's and Sumitomo's [DBM] prices and allocating their respective [DBM] accounts in the U.S." (Direct CAC ¶ 34; Indirect CAC ¶ 42), and (3) attended the 2004 Tulsa meeting where (i) Mr. Akiyama of Sumitomo recounted to him "multiple discussions" between him and Mr. Ahl to set DBM prices and allocate DBM markets "and ensure that Sumitomo was

maintaining its agreement with Premier to fix [DBM] prices and allocate [DBM] markets," (Direct CAC ¶ 40; Indirect CAC ¶) and (ii) it was revealed that Sumitomo communicates with Premier on a daily basis fix prices and allocate accounts. These allegations create a plausible inference that YAS had knowledge of an agreement to fix prices in and allocate shares of the domestic DBM market and the intent to join it. Accepting Plaintiff's allegations as true and making all reasonable inferences in their favor, YAS' facilitation of Sumitomo's DBM purchasing indicates a plausible stake in the DBM Agreement, while its receipt of phone calls to discuss the Agreement and attendance at a meeting at which it was revealed indicates that YAS had knowledge of the DBM Agreement and that it engaged in informed and interested cooperation.

*18 Citing to *In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 (2d Cir.2007) and *Hinds County, Mississippi v. Wachovia Bank N.A.*, 620 F.Supp.2d 499, 518 (S.D.N.Y.2009), YAS argues that these allegations should be "discounted" because they amount to mere "averments of agreements made at some unidentified place and time." (YAS Br., 4.) *In re Elevator Antitrust Litig.* concerned a list of "basically every type of conspiratorial activity that one could imagine ... in entirely general terms without any specification of any particular activities by any particular defendant." 502 F.3d at 50. Similarly, *Hinds County* dealt with conclusory allegations of "'per se illegal horizontal communications' in support of [an] alleged conspiracy." 620 F.Supp.2d at 518. Here, in contrast, Plaintiffs allege (1) the way in which YAS participates with Sumitomo—a member of the conspiracy—in the domestic DBM market, (2) phone calls from Premier—another party to the conspiracy—to YAS to discuss fixing prices in and allocating shares of the domestic DBM market, and (3) YAS's attendance at a meeting where Sumitomo—its partner in the domestic DBM market—recounted to YAS discussions in which it set prices in and allocated shares of the domestic DBM market with Premier. These allegations, do not amount to a mere "list of theoretical possibilities," *In re Elevator Antitrust Litig.*, 502 F.3d at 50, or "require the Court to assume the existence of the conspiracy." *Hinds County*, 620 F.Supp.2d at 518. Rather, they make the alleged conspiracy more plausible.

YAS further argues that "it is wholly implausible that [it] (a minor player that was not itself a manufacturer, importer or seller¹⁷) would have discussed fixing Premier's and Sumitomo's [DBM] prices," particularly since Plaintiffs fail to "allege that YAS had any ability to influence (let alone)

dictate Sumitomo's [DBM] prices, nor which customers Sumitomo dealt with." (YAS Br., 5.) As previously discussed, this line of argument is not only improper at the pleading stage—where the Court must accept Plaintiffs' allegations as true—it is also unpersuasive. There is nothing "wholly implausible" about YAS participating in discussions to fix prices in and allocate shares of the domestic DBM market. Sumitomo was only able to participate in the domestic DBM market in the first place due to YAS's relationship with Chinese mines from which Sumitomo could purchase DBM and magnesite. Consequently, it is certainly plausible that YAS could participate in discussions with co-conspirators to fix prices and allocate shares of the DBM market.

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Citing to *Howard Hess Dental Laboratories Inc. v. Dentsply Intern., Inc.*, 424 F.3d 363 (3d Cir.2005), YAS also argues that Plaintiffs' failure to allege that it sold DBM or CCM requires its dismissal from this case as a matter of law. While that case notes the well-settled proposition that only direct purchasers may recover damages in federal antitrust suits, it by no means indicates that only a seller of the product in question may be found liable in a [Section 1](#) conspiracy. As previously discussed, YAS need not have participated in a particular act in furtherance of the conspiracy to be held liable.

2. The CCM Agreement

Plaintiffs' allegations suggesting an agreement among Sumitomo and Premier to allocate the CCM market to Premier apply with equal force to YAS. As previously discussed, Plaintiffs allege that (1) Sumitomo and YAS met with others at a Tulsa hotel, in the summer of 2004, to discuss entering the domestic CCM market in order to fill Sumitomo's barge capacity; (2) Premier discovered their plan to enter the domestic CCM market and retaliated by lowering DBM prices to keep Sumitomo and YAS out of the CCM market; and (3) as a result, Sumitomo and YAS agreed with Premier to remain out of the CCM market.

*19 YAS argues that these allegations are conclusory because they "provide [] no details whatsoever about YAS's participation in this alleged agreement, including what role it is alleged to have played." (YAS Br., 7.) At the pleading stage, however, Plaintiffs need not allege the specific nature of YAS's or any other Defendant's participation in the agreement to allocate the CCM market to Premier. See *In re Static Random Access Memory (SRAM) Antitrust Litig.*, 580 F.Supp.2d 896, 904 (N.D.Cal.2008) ("Although

Plaintiffs will need to provide evidence of each Defendants' participation [at summary judgment] ... they now only need to make allegations that plausibly suggest that each Defendant participated in the alleged conspiracy."). As previously discussed, Plaintiffs must set forth allegations suggesting that YAS had knowledge of the agreement and the intent to join it. Plaintiffs' allegations that YAS, as Sumitomo's partner in the domestic MgO market, (1) attended a meeting to arrange for Sumitomo to enter the domestic CCM market and (2) subsequently agreed with Sumitomo and Premier to allocate that market to Premier in order to maintain their agreement to fix prices and allocate shares of the domestic DBM market, do just that.

Finally, like Sumitomo, YAS argues that it cannot be held liable for the alleged agreement to allocate the domestic CCM market to Premier because Plaintiffs fail to establish that YAS was an actual or potential competitor in that market. For the reasons discussed in Point IICiv, at the pleading stage, Plaintiffs, as purchasers, need not establish that YAS was an actual or potential competitor in the CCM market in order to allege its participation in a horizontal conspiracy. Furthermore, YAS's (1) role in facilitating Sumitomo's purchase of Chinese DBM and (2) attendance at the 2004 Tulsa meeting where it, Sumitomo, and the Vannorsdels discussed entering into the CCM market, suggests that YAS intended to participate with Sumitomo in the CCM market in the same way as they had been participating in the DBM market. Thus, Plaintiffs have set forth allegations plausibly suggesting that YAS participated in an agreement to allocate the CCM market to Premier.

D. Statute of Limitations and Fraudulent Concealment

Actions brought under the Clayton Act are subject to a four-year statute of limitations. 15 U.S.C. § 15b. In an antitrust conspiracy that continues over a period of years, each overt act in furtherance thereof that injures the plaintiff—for example, the selling of a price-fixed product—starts the statute of limitations period running for that particular act. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189, 117 S.Ct. 1984, 138 L.Ed.2d 373 (1997); *see also Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338, 91 S.Ct. 795, 28 L.Ed.2d 77 ("Generally, a cause of action accrues and the statute begins to run when a defendant commits an act that injures a plaintiff's business" (citations omitted)). However, "the commission of a separate new overt act generally does not permit the plaintiff to recover for the injury caused by old overt acts outside the limitations period." *Klehr*, 521 U.S. at 190 (citations omitted).

*20 Defendants argue that Plaintiffs' federal antitrust claims are barred by the applicable four-year statute of limitations. Specifically, Defendants contend that Plaintiffs (1) fail to allege overt acts in furtherance of the alleged conspiracy that occurred after 2004 and (2) fail to plead fraudulent concealment with particularity to otherwise toll the statute of limitations. Plaintiffs do not dispute that they fail to allege overt acts after 2004, but maintain that they plead fraudulent concealment with the requisite particularity to toll the statute of limitations.

The equitable doctrine of fraudulent concealment applies to every federal statute of limitations. *Holmberg v. Armbrecht*, 327 U.S. 392, 397, 66 S.Ct. 582, 90 L.Ed. 743 (1946). To toll a statute of limitations through fraudulent concealment, a plaintiff must show "(1) an affirmative act of concealment; (2) which misleads or relaxes the plaintiff's inquiry, who (3) exercised due diligence in investigating his cause of action ." *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1178–79 (3d Cir.1993) (citation omitted). In addition, allegations of fraudulent concealment must be pled with particularity in accordance with Federal Rule of Civil Procedure 9(b). *In re Mercedes-Benz*, 157 F.Supp.2d at 368.

However, "Rule 9[(b)] does not require plaintiffs to plead facts that, by the nature of the alleged fraud, are within the defendants' control." *Id.* (citing *In re Craftmatic Secs. Litig.*, 890 F.2d 628, 645 (3d Cir.1989)). Indeed, "[c]ourts must be sensitive to the fact that [a rigid] application of Rule 9(b) prior to discovery may permit sophisticated defrauders to successfully conceal the details of their fraud." *In re Craftmatic*, 890 F.2d at 645 (quotation and citation omitted). "Thus, courts have relaxed the rule when factual information is peculiarly within the defendant's knowledge or control." *Id.* Accordingly, under the more flexible application of Rule 9(b), Plaintiffs need not allege the specific information that is exclusively within Defendants' knowledge or control. *See id.* at 646. However, Plaintiffs must allege facts suggesting fraudulent concealment and "why additional information lies exclusively within the defendants' control." *Id.*

As discussed fully below, Plaintiffs fail to satisfy each element of fraudulent concealment, thus requiring dismissal of their federal antitrust claims as time-barred. However, the Court will grant Plaintiffs leave to amend their allegations of fraudulent concealment to equitably toll the statute of limitations.¹⁸

18 IP Plaintiffs' state antitrust law claims similarly require dismissal for failure to establish fraudulent concealment, as their applicable statutes of limitations range from three to six years. *See Ariz.Rev.Stat. Ann. § 44-1410(A)* (Arizona) (2011) (four years); *Cal. Bus. & Prof.Code § 16750.1* (2011) (California) (four years); *D.C.Code § 28-4511(b)* (2011) (four years); *Haw.Rev.Stat. § 480-24(a)* (2010) (Hawaii) (four years); *Ill. Comp. Stat. ch. 740, § 10/7(2)* (2010) (four years); *Iowa Code § 553.16* (2011) (Iowa) (four years); *Four B Corp. v. Daicel Chem. Indus., Ltd.*, 253 F.Supp.2d 1147, 1156 (D.Kan.2003) (Kansas) (three years) (citing Kan. Stat. Ann. § 60-512(2) (2010)); *McKinnon v. Honeywell Int'l, Inc.*, 977 A.2d 420, 424 (Me.2009) (Maine) (six years) (citing Me.Rev.Stat. Ann. tit. 14 § 752 (2008)); *Mich. Comp. Laws § 445.781* (2010) (Michigan) (four years); *Am. Computer Trust Leasing v. Jack Farrell Implement Co.*, 763 F.Supp. 1473, 1491 n. 21 (D.Minn.1991) (Minnesota) (four years) (citing Minn.Stat. § 325D.64 (subdiv .1) (2010)); *Miss.Code Ann. § 15-1-49(1)* (2010) (three years); *Neb.Rev.Stat. § 25-206* (2010) (Nebraska) (four years); *Nev.Rev.Stat. § 598A.220(2)(a)* (2010) (four years); *N.H.Rev.Stat. § 356:12(II)* (1973) (New Hampshire) (four years); *N.M. Stat. § 57-1-12(B)* (1978) (New Mexico) (four years); *N.Y. Gen. Bus. Law § 340(5)* (2004) (New York) (four years); *N.C. Gen.Stat. § 75-16.2* (2010) (North Carolina) (four years); *N.D. Century Code § 51-08.1-10(2)* (1987) (four years); *Or.Rev.Stat. § 646.800(2)* (1975) (Oregon) (four years); *S.D. Codified Laws § 37-1-14.4* (1975) (South Dakota) (four years); *State ex rel. Leech v. Levi Strauss & Co.*, No. 79-722-III, 1980 WL 4696, at *3 (Tenn.Ch. Sept.25, 1980) (Tennessee) (three years) (citing Tenn. Stat. § 28-3-105(3) (2011)); *Utah Code § 76-10-925(2)* (1979) (Utah) (four years); *Vt. Stat. Ann. tit. 12, § 511* (2010) (Vermont) (six years); *W. Va.Code § 47-18-11* (1978) (West Virginia) (four years); *Wis. Stat. § 133.18(2)* (2011) (Wisconsin) (six years). However, to the extent that IP Plaintiffs sufficiently amend their allegations to establish fraudulent concealment of their federal antitrust claims, they will also have established fraudulent concealment of their state law antitrust claims. *See Note 9.*

i. Affirmative Acts of Concealment

Defendants argue that (1) Plaintiffs fail to sufficiently allege affirmative acts of concealment and (2) their allegations that the MgO conspiracy is self-concealing cannot satisfy the first element of fraudulent concealment.¹⁹ Plaintiffs contend that they have alleged (1) a self-concealing conspiracy that satisfies the first element of fraudulent concealment, or, (2) in the alternative, affirmative acts of concealment committed by Defendants.

19 Defendants further argue that Sumitomo's alleged admission to the Vannorsdels of the DBM Agreement cuts against their fraudulent concealment allegations. This is unpersuasive because the admission in no way put Plaintiffs on notice of their claims during the limitations period. *See Emerson Elec. Co. v. Le Carbon Lorraine, SA*, 500 F.Supp.2d 437, 448 (D.N.J.2007) ("Where fraudulent concealment of a federal antitrust claim has been shown, the four-year federal statute of limitations begins anew from the time the plaintiff knew or should have known of the existence of the federal claim." (quotations and citations omitted)).

*21 The Court of Appeals has yet to define what constitutes an affirmative act of concealment in antitrust cases. However, courts have generally taken two distinct views. *In re Mercedes-Benz*, 157 F.Supp.2d at 368. The first requires a plaintiff to show one or more affirmative acts to conceal an antitrust conspiracy that are wholly extrinsic to the conspiracy itself. *See, e.g., Colorado v. Western Paving Constr. Co.*, 630 F.Supp. 206, 2010 (D.Colo.1986), *aff'd en banc by an equally divided court*, 841 F.2d 1025 (10th Cir.1988), *cert. denied*, 488 U.S. 870, 109 S.Ct. 179, 102 L.Ed.2d 148 (1988). The second also requires a plaintiff to show one or more affirmative acts of concealment, but those acts may be part and parcel to, or in furtherance of, the conspiracy. *Supermarket of Marlington, Inc. v. Meadow Gold Dairies, Inc.*, 71 F.3d 119, 122 (4th Cir.1995) (citing *Texas v. Allen Constr. Co.*, 851 F.2d 1526, 1532 (5th Cir.1988)). The Court finds the first view to be overly restrictive in this case. In a conspiracy involving price-fixing, "it is virtually impossible to distinguish between acts in furtherance of the conspiracy and acts designed to maintain the conspiracy's secrecy because the conspiracy's success is often contingent upon its ability to avoid detection by regulators and purchasers." *In re Aspartame Antitrust Litig.*, No. 06-1732, 2007 WL 5215231, at *5 (E.D.Pa. Jan.18, 2007); *See also In re Mercedes-Benz*,

157 F.Supp.2d at 372 (“secrecy is [the] natural lair” of a price-fixing conspiracy).

Several courts, including those in this Circuit, have found that a plaintiff may avoid the affirmative act requirement altogether in cases where an antitrust conspiracy is “inherently self-concealing.” See, e.g., *In re Aspartame*, 2007 WL 5215231, at *5; *In re Nine West Shoes Antitrust Litig.*, 80 F.Supp.2d 181, 192 (S.D.N.Y.2000); *In re Mercedes-Benz*, 157 F.Supp.2d at 371; *Pennsylvania Milk Indus. Mgmt. Corp.*, 812 F.Supp. 500 (E.D.Pa.1992); *Bethlehem Steel Corp. v. Fischbach & Moore, Inc.*, 641 F.Supp. 271, 273–74 (E.D.Pa.1986). However, the definition of a self-concealing antitrust conspiracy, particularly one that involves price-fixing, remains nebulous. The *In re Mercedes-Benz* court held that a self-concealing antitrust conspiracy is one where “concealment is so intertwined with the conspiracy as a whole that the equitable foundations of the fraudulent concealment doctrine require the limitations period to be tolled.” 157 F.Supp.2d at 371. Other courts maintain that all properly alleged price-fixing conspiracies are inherently self-concealing. See, e.g., *In re Issuer Plaintiff Initial Public Offering Antitrust Litig.*, No. 00-7804, 2004 WL 487222, at *4 (S.D.N.Y. Mar.12, 2004); *Nine West*, 80 F.Supp.2d at 192.

The Court agrees that, under certain circumstances, an antitrust conspiracy may depend on its own concealment to the point that any act in furtherance thereof can also be said to conceal it. As the Supreme Court explained long ago, the purpose of the fraudulent-concealment doctrine is to prevent a defendant from “concealing a fraud, or ... committing a fraud in a manner that it concealed itself until such time as the party committing the fraud could plead the statute of limitations to protect it.” *Bailey v. Glover*, 88 U.S. (21 Wall.) 342, 349, 22 L.Ed. 636 (1874). However, the Court cannot find that conspiracies involving price-fixing are *per se* self-concealing, as such a finding would render them wholly exempt from the applicable statute of limitations.

*22 Although not binding, *In re Publication Paper Antitrust Litig.*, No. 04-1631, 2005 WL 2175139 (D.Conn. Sept.7, 2005) provides a helpful framework under which to determine whether a conspiracy involving price-fixing is self-concealing for the purposes of establishing fraudulent concealment. That case found that a price-fixing conspiracy may be self-concealing, depending on the nature of the industry in which the item is price-fixed:

In a competitive, well-regulated industry it will often be the case that a price-fixing conspiracy, if not concealed, would immediately fail because of governmental or private legal action. In such circumstances, any announcement of a price increase will carry with it an implicit statement that the price increase is legitimate, i.e., the result of competitive forces, not collusion. Nevertheless, not every price-fixing conspiracy is self-concealing. For example, there may be industries in which the participants are aware of collusion but it is not stopped because of indifference, fear, or because the perpetrators are exempt from, or beyond the reach of, antitrust laws. In such circumstances, the defendants' announcement of a price increase will not carry with it any implied certification of legitimacy, and so, absent additional circumstances, will not be self-concealing.

In re Publication Paper, 2005 WL 2175139, at *4. Accordingly, “whether a particular price-fixing conspiracy or, more precisely, whether a particular announcement of a price increase necessarily conceals its true nature depends on the nature of the industry and the circumstances surrounding the announcement.” *Id.* In other words, a plaintiff must show circumstances indicating that a price increase “carries with it a pretense of legitimacy” or “that it would necessarily be assumed that [it was] the result of legitimate market forces.” *Id.* To do so, a plaintiff may, for example, set forth allegations showing “that price increases are not abnormal, that such increases are typically ascribed to market forces, that an openly collusive price increase would not be tolerated, and that there was nothing suspicious about the circumstances under which each of the pre-limitations period price announcements were made.” *Id.*

Here, Plaintiffs fail to allege particular circumstances surrounding the MgO market indicating that the alleged conspiracy was self-concealing. Plaintiffs come close to pleading an affirmative act of concealment in alleging that

“price increases for MgO were justified by references to tight supply, thinning margins, and increased energy and freight costs” (Direct CAC ¶ 51; Indirect CAC ¶ 58), however they fail to explain the particular circumstances surrounding Defendants’ price increases and pretextual justifications for those increases—information which is in Plaintiffs’ control—in accordance with Rule 9(b).²⁰ Thus, Plaintiffs have failed to meet the first element of fraudulent concealment to toll the statute of limitations. However, the Court will grant Plaintiffs leave to amend to adequately plead either (1) circumstances surrounding the MgO market during the Class Period indicating that the alleged conspiracy is self-concealing, or (2) particular circumstances surrounding Defendants’ price increases and the allegedly pretextual justifications for those price increases. *See In re Burlington Coat Factory Litig.*, 114 F.3d at 1434.

²⁰ Nor can Plaintiffs’ conclusory allegation that “defendants met secretly and among themselves for the express purpose of fixing prices and allocating markets of domestically sold MgO” (Direct CAC ¶ 50; Indirect CAC ¶ 57) satisfy the affirmative act requirement.

ii. Reliance

*23 Defendants argue that Plaintiffs fail to meet the second element of fraudulent concealment because they have not alleged that they relied on Defendants’ alleged affirmative acts of concealment. Plaintiffs argue that there is no reliance requirement to establish fraudulent concealment.

While the aforementioned elements of fraudulent concealment do not specifically note a reliance requirement, the language of the second element strongly suggests one. As previously noted, the second element of fraudulent concealment requires a showing that the defendant’s concealment misled or relaxed the plaintiff’s potential inquiry into what otherwise would have been evidence of its cause of action. *In re Lower Lake Erie*, 998 F.2d at 1179; *see also Forbes v. Eagleton*, 228 F.3d 471, 487 (3d Cir.2000) (“[T]he plaintiff must show that he actually was mis[led] ... into thinking that he d [id] not have a cause of action” (quotation and citation omitted)). Implicit in the notion that a plaintiff’s inquiry was misled or relaxed by an act of concealment is that the plaintiff relied on that act of concealment. That is, the plaintiff’s inquiry would not have been misled or relaxed if it did not rely on the defendant’s act of concealment. Here, Plaintiffs make no allegations that they were misled by Defendants’ concealment of the alleged conspiracy and

therefore have failed to meet the second element of fraudulent concealment. However, the Court will grant Plaintiffs leave to amend to adequately plead that they relied on the self-concealing nature of Defendants’ conspiracy and/or pretextual justifications for Defendants’ price increases. *See In re Burlington Coat Factory Litig.*, 114 F.3d at 1434.

iii. Due Diligence

Defendants argue that Plaintiffs fail to satisfy the due diligence element of fraudulent concealment because they do not allege any due diligence performed during the Class Period, particularly that which led to the discovery of the alleged conspiracy. Plaintiffs counter that, under the fraudulent concealment doctrine, they need only plead that they would not have discovered their claim, even in the exercise of reasonable due diligence. Plaintiffs further argue that determinations of due diligence are fact-intensive and therefore not properly addressed on a motion to dismiss.

The parties cite somewhat differently worded standards to support their respective positions on what the due diligence prong requires. Defendants cite *In re Lower Lake Erie*, in which the Court of Appeals held that a plaintiff must show that he “exercised due diligence in investigating his cause of action.” 998 F.2d at 1178–79. Plaintiffs, on the other hand cite *Matthews v. Kidder, Peabody & Co., Inc.*, where the Court of Appeals held that a plaintiff must show that his ignorance is not attributable to a lack of “reasonable due diligence in attempting to uncover the relevant facts.” 260 F.3d 239, 256 (3d Cir.2001).

While the wording of the due diligence prong has differed slightly among Third Circuit case law, its substance has remained consistent. The due diligence prong is rooted in the notion of inquiry notice: that an injury accrues when a reasonable plaintiff under the circumstances would have discovered it. *See Matthews*, 260 F.3d at 251. As previously discussed, a federal antitrust injury accrues when an overt act is committed that injures the plaintiff, thereby triggering the four-year statute of limitations; however, one or more affirmative acts of concealment “may toll the statute of limitations [] if [they] mislead[] a plaintiff into thinking that he does not have a cause of action.” *Davis v. Grusemeyer*, 996 F.2d 617, 624 (3d Cir.1993), *overruled on other grounds by Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644 (3d Cir.1998). Thus, to establish the due diligence prong of fraudulent concealment, a plaintiff must affirmatively show that he was not on inquiry notice of the alleged antitrust conspiracy. *See id.* (“A key aspect of a plaintiff’s case alleging

fraudulent concealment is [] proof that the plaintiff was not previously on notice of the claim he now brings.” (citations omitted)).

*24 In this Circuit, “inquiry notice [is] analyzed in two steps.”²¹ *Matthews*, 260 F.3d at 252. “First, the burden is on the defendant [s] to show the existence of ‘storm warnings.’ “ *Id.* In this case, a storm warning would be information or data that would alert a reasonable MgO purchaser of ordinary intelligence to potentially culpable conduct. “Second, if the defendants establish the existence of storm warnings, the burden shifts to the plaintiffs to show that they exercised reasonable due diligence and yet were unable to discover their injuries.” *Id.* This requires Plaintiffs to show that (1) they investigated the storm warnings and (2) in their investigation, they exercised the due diligence expected of a reasonable DBM or CCM purchaser of ordinary intelligence. *See id.*

²¹ While the following inquiry notice analysis is laid out in the context of a RICO case, it has also been applied in antitrust cases involving price-fixing. *See In re Aspartame Antitrust Litig.*, 416 Fed. App'x. 208, 211–12 (3d Cir.2011); *In re Electrical Carbon Prods. Antitrust Litig.*, 333 F.Supp.2d 303, 317 (D.N.J.2004).

As Plaintiffs point out, this inquiry is necessarily bound up with the facts of the case because it “implicates factual questions as to when [a] plaintiff discovered or should have discovered the elements of the cause of action,” *id.* at 250 (quotations and citation omitted); *see also Mercedes-Benz*, 157 F.Supp.2d at 373 (“At a minimum, this issue will involve assessing the factual circumstances surrounding the accused purchasing transactions and whether those circumstances would have put a reasonably diligent plaintiff on notice of a price-fixing conspiracy”), and, as a result, at the pleading stage, this court has been hesitant to dismiss an otherwise fraudulently concealed antitrust claim for failure to sufficiently allege due diligence. *See In re Electrical Carbon Prods.*, 333 F.Supp.2d at 317–18; *Mercedes-Benz*, 157 F.Supp.2d at 374.

Citing to *In re Publication Paper* and *Hinds County*, Defendants maintain that, at the pleading stage, the due diligence prong nonetheless requires that “Plaintiffs [] allege with particularity when the Named Plaintiffs or Class members became aware of the antitrust violations and what inquiries [they] made into the activities alleged in the complaint.” (Sumitomo Reply Br., 18) (internal quotations

omitted). In *In re Publication Paper*, the plaintiffs alleged that they were aware of certain suspicious activities two years before the end of the limitations period. *See 2005 WL 2175139*, at *5. Accordingly, the court found that the plaintiffs were therefore required to allege the steps they took to investigate those activities. *See id.* Here, however, Plaintiffs do not allege any suspicious activities or storm warnings within the limitations period.

Defendants' citation to *Hinds County* is more persuasive. In that case, the plaintiffs attempted to satisfy the due diligence prong by alleging that they “did not discover, nor could have discovered through reasonable diligence, that [d]efendants and their co-conspirators were violating the antitrust laws until shortly before this litigation was commenced, because [d]efendants and their co-conspirators were using deceptive and secret methods to avoid detection and affirmatively conceal their violations.” *Hinds County*, 620 F.Supp.2d at 521–22. The court found that allegation too vague to satisfy Rule 9(b) and further explained that to deem such an allegation sufficient would “allow[] the allegations required to satisfy the first prong of fraudulent concealment to also satisfy the third prong.” *Id.* at 521–22.

*25 The Court finds this logic persuasive. Here, Plaintiffs allege that, due to the secretive nature of the alleged MgO conspiracy, “neither plaintiffs nor the class members had knowledge of any of the foregoing violations, and neither plaintiffs nor the class members, until recently, could have discovered through reasonable diligence that [D]efendants and their co-conspirators had engaged in the foregoing violations.” (Direct CAC ¶ 49; Indirect CAC ¶ 56.) This allegation cannot satisfy the requirements of Rule 9(b), particularly when it fails to encompass when and how Plaintiffs ultimately discovered the alleged MgO conspiracy—information that is certainly within Plaintiffs' control. *See In re Craftmatic*, 890 F.2d at 645. Without some level of specificity regarding Plaintiffs' discovery of the alleged conspiracy, it is impossible to discern whether Plaintiffs could or should have discovered it within the limitations period. Thus, Plaintiffs have failed to meet the due diligence prong of fraudulent concealment. However, Plaintiffs will be granted leave to amend to adequately plead, in accordance with Rule 9(b), (1) when and how they discovered the alleged MgO conspiracy, and (2) that the self-concealing nature of the conspiracy and/or pretextual justifications for Defendants' price increases made it so that they were not alerted to any storm warnings that would otherwise trigger an obligation

to perform due diligence. *See In re Burlington Coat Factory Litig.*, 114 F.3d at 1434.

E. IP Plaintiffs' Claims for Violations of Various States' Consumer Protection Laws

IP Plaintiffs assert claims under California, Florida, Hawaii, Massachusetts, Montana, Nebraska, New Hampshire, New York, South Carolina, and Vermont consumer protection and unfair competition laws. As with IP Plaintiffs' antitrust claims under state law, Defendants argue that IP Plaintiffs lack standing to assert their consumer protection claims, except that under California law, because they "do not allege purchases in any of the 10 states other than California." (Sumitomo (IP Pl.'s) Br., 5). Defendants further argue that these claims should be dismissed because IP Plaintiffs do not plead them with particularity in accordance with **Federal Rule of Civil Procedure 9(b)**.

i. Standing

IP Plaintiffs' standing to sue under a state's consumer protection law is analogous to their standing under a state's antitrust law. As discussed in Point B, IP Plaintiffs' failure to tie their injuries or Defendants' unlawful conduct to a number of states was fatal to their standing to sue because the antitrust laws of those states require a showing that part of Defendants' conduct occurred or had an effect in-state. On the other hand, IP Plaintiffs have standing to sue under the antitrust laws that have no such requirement.

Similarly, many of the consumer protection and unfair competition laws asserted by IP Plaintiffs require that Defendants' unlawful conduct affect trade and commerce in the state under whose law they are suing, *see MCA 30–14–103, 102* (Montana) ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful.... [T]rade or commerce [must] directly or indirectly affect[] the people of this state."); *MGLA §§ 93A 1, 2* (Massachusetts) (same); *S.C.Code 1976 §§ 39–5–10, 20* (South Carolina) (same); *Neb. Rev. St. §§ 59–1602, 1601* (Nebraska) ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce shall be unlawful.... Trade and commerce shall mean the sale of assets or services and any commerce directly or indirectly affecting the people of the State of Nebraska."); *N.H.Rev.Stat. § 358–A:2* (New Hampshire) ("It shall be unlawful for any person to use any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state.");

N.Y. Gen. Bus. Law § 349 (New York) ("Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful."); *Sherman v. Ben & Jerry's Franchising, Inc.*, 08–CV–207, 2009 WL 2462539, at *10 (D.Vt. Aug.10, 2009) (Out of state plaintiffs alleging out of state conduct do not have standing to sue under Vermont Consumer Fraud Protection Act), while others do not, *see F.S.A. 501.204, 501.211* (Florida); *HRS 480–2, 480–13* (Hawaii).²²

22

Thus, contrary to Defendants' contention, the fact that IP Plaintiffs fail to allege that they reside or purchased an MgO product in a given state does not automatically deprive them of standing to sue under the state's consumer protection or unfair competition law. To be sure, the case Defendants cite in support of this contention held that the named plaintiffs in that case lacked standing to assert consumer protection and unfair competition claims under the laws of states in which they neither resided nor suffered an injury. *See In re Potash* 667 F.Supp.2d at 924. However, the Court cannot accept this holding as a bright line rule. Standing issues are intimately bound up with the elements of the particular claim asserted, as a plaintiff must establish that his injury is "fairly traceable to the challenged action of the defendant." *Lujan*, 504 U.S. at 560; *see also Blum*, 457 U.S. at 999 ("The complaining party must also show that he is within the class of persons who will be concretely affected."); *Allen*, 468 U.S. at 752 ("[T]he standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted.").

*26 IP Plaintiffs' allegations that "Defendants agreed to, and did in fact, act in restraint of trade or commerce in a market that includes the above states, by affecting, fixing, controlling, and/or maintaining, at artificial and noncompetitive levels, the prices at which MgO and MgO Products were sold, distributed, or obtained in those states;" "MgO price competition was restrained, suppressed, and eliminated throughout the states;" and "MgO prices were raised, fixed, maintained, and stabilized at artificially high levels throughout the states" (Indirect CAC ¶¶ 79, 81) are conclusory and do not tie their injuries to the alleged conspiracy's effect on trade and commerce in those specific states. Therefore, IP Plaintiffs' consumer protection claims

under Montana, Massachusetts, Nebraska, New Hampshire, and New York law are dismissed for lack of standing.

ii. Pleading Requirements

The consumer protection laws of Florida and Hawaii—under which IP Plaintiffs currently maintain standing to sue—require that they plead the circumstances of any alleged fraudulent conduct with particularity in accordance with Rule 9(b). See *Jovine v. Abbott Laboratories, Inc.*, 11-CV-80111, 2011 WL 1376029 (S.D.Fla. Apr.12, 2011) (applying Rule 9(b) to allegations of unfair or deceptive acts or practices under the Florida Deceptive and Unfair Trade Practices Act); *Cannon v. U.S. Bank, NA*, Civ. No. 11-00079, 2011 WL 1637415, (D.Hawai'i Apr.29, 2011) (applying Rule 9(b) to allegations of fraudulent business practices under the Hawaii State Unfair and Deceptive Business Practices Act); *Athena Feminine Techs., Inc. v. Wilkes*, No. C 10-4868, 2011 WL 4079927 (N.D.Cal. Sept.13, 2011) (“[A] claim brought under the fraudulent prong of the [Unfair Competition Law] must be pled with particularity under Rule 9(b)”).

IP Plaintiffs' allegations that “Defendants deliberately failed to disclose material facts to Plaintiff and the classes concerning Defendants' unlawful activities and artificially inflated prices for MgO and MgO Products,” and “misrepresented to all consumers during the Class Period that Defendants' MgO prices were competitive and fair” (Indirect CAC ¶ 80); *see also* (Indirect CAC ¶ 83) (alleging “affirmative misrepresentations and omissions concerning the price of MgO”) are not set forth with any measure of particularity. See *In re Supreme Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 270 (3d Cir.2006) (Under Rule 9(b), a plaintiff must allege fraud with particularity by pleading the following: “(1) a specific false representation [or omission] of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his [or her] damage.” (quotations and citation omitted)). Accordingly, IP Plaintiffs' consumer protection and unfair competition claims under Florida and Hawaii law are dismissed to the extent they are premised on Defendants' fraudulent conduct. However, IP Plaintiffs are granted leave to amend their allegations to comply with the requirements of Rule 9(b). Additionally, at this time, those claims may move forward to the extent they are premised on allegations of Defendants' engaging in unfair competition, as there is no indication that Rule 9(b) applies to such allegations.

III. CONCLUSION

*27 For the foregoing reasons, Defendants' Motion to Dismiss is GRANTED to the following extent only. The Court rules as follows:

- (1) IP Plaintiffs' federal and state antitrust claims are dismissed without prejudice for lack of standing. IP Plaintiffs have thirty (30) days to amend their allegations to set forth (1) the specific products purchased containing DBM or CCM and (2) the nexus between an increase in the price of those products and the alleged conspiracy to fix prices in and allocate shares of the domestic DBM and CCM markets.
- (2) IP Plaintiffs' antitrust claims under Arizona, the District of Columbia, Hawaii, Illinois, Maine, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, and West Virginia law are dismissed with prejudice for lack of standing.
- (3) Plaintiffs' federal and state antitrust claims are dismissed without prejudice as time-barred under the applicable statutes of limitations. Plaintiffs have thirty (30) days to amend their allegations of fraudulent concealment to equitably toll those statutes of limitations.
- (4) IP Plaintiffs' consumer protection and unfair competition claims under Montana, Massachusetts, Nebraska, New Hampshire, and New York are dismissed with prejudice for lack of standing.
- (5) IP Plaintiffs' consumer protection and unfair competition claims under Florida and Hawaii law are dismissed without prejudice to the extent they are premised on allegations of Defendants' fraudulent conduct. IP Plaintiffs have thirty (30) days to amend those allegations to comply with *Federal Rule of Civil Procedure 9(b)*.

The Court will enter an order implementing this opinion.

All Citations

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TAB 31

2012 WL 3582708

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United States District Court,
N.D. Illinois,
Eastern Division.

In re ZIMMER NEXGEN KNEE IMPLANT
PRODUCTS LIABILITY LITIGATION.
This Document Relates to All Cases.

MDL No. 2272.

Master Docket No. 11 C 5468.
Aug. 16, 2012.

MEMORANDUM OPINION AND ORDER

REBECCA R. PALLMEYER, District Judge.

*1 Plaintiffs, more than 500 individuals who underwent **total knee replacement** (“TKR”) surgeries, bring suit against Defendants, Zimmer Inc. and its affiliates (collectively, “Defendants” or “Zimmer”), manufacturers of the Zimmer NexGen Knee system. Plaintiffs allege that certain components of that system are prone to premature loosening, which has led to pain and loss of movement, necessitating revision surgery in some cases. On August 8, 2011, the United States Judicial Panel on Multidistrict Litigation issued a transfer order consolidating Plaintiffs' cases in this court for pretrial proceedings.

Pursuant to this court's Order of December 19, 2011, Plaintiffs filed a Master Long Form Complaint and Jury Demand (the “Master Complaint”) on January 12, 2012. Defendants filed a motion to dismiss, in part, the Master Complaint on March 14, 2012. For the reasons explained below, Defendants' motion is denied.

BACKGROUND¹

¹ Though the court primarily draws Plaintiffs' factual allegations from the Master Complaint, the court is not confined to the four corners of the complaint. See *Geinosky v. City of Chicago*, 675 F.3d 743, 745 n. 1 (7th Cir.2012) (“[A] party opposing a Rule

12(b)(6) motion may submit materials outside the pleadings to illustrate the facts the party expects to be able to prove.”). The court also considers factual allegations consistent with the pleadings presented in Plaintiffs' Technical Memorandum on Knee Anatomy, Total Knee Replacement and the Zimmer NexGen High-Flexion Components and MIS Surgical Technique [210] (hereinafter “Pls.' Technical Mem.”), Plaintiffs' scientific presentation to the court on January 12, 2012, and Plaintiffs' Memorandum in Opposition to Defendants Zimmer Entities' Motion to Dismiss, In Part, Master Long Form Complaint and Jury Demand [428] (hereinafter “Pls.' Resp.”).

Plaintiffs' claims involve a tibial component designed for use with minimally invasive surgery techniques (the “MIS Tibial component”), and four “high-flex” femoral components (the Cruciate Retaining (CR) Flex and Legacy Posterior Stabilized (LPS) Flex components, and the “Gender Solutions” versions thereof (collectively, the “Flex femoral components”)). (Master Long Form Compl. & Jury Demand [211] (hereinafter, “Master Compl.”), ¶ 7.)² According to Plaintiffs, the MIS Tibial component, approved by the FDA in 2005, was a “low profile design” intended to be implanted using a smaller incision, with the benefits of reduced blood loss, less pain, shorter hospital stays, and shorter rehabilitation. (*Id.* ¶¶ 64, 88.) In 2010, after a study found a significantly higher failure rate among MIS Tibial components when implanted without a drop-down stem that extended further into the tibia (*id.* ¶ 149), and after Zimmer had received complaints of loosening of the implanted devices requiring revision surgery (*id.* ¶ 155), Zimmer issued an “Urgent Field Safety Notice”/ “Urgent Device Correction” letter to all customers using the MIS Tibial component (*id.* ¶ 115). The letter cautioned that the “MIS procedures are inherently challenging and can involve reduced visibility, which may lead to difficulty with achieving proper implant alignment and cement fixation” (*id.* ¶ 115), and further warned against implanting the device without the drop-down stem (Pls.' Technical Mem. at 13). In September of 2010, the FDA classified Zimmer's response as a Class II recall of more than 68,000 MIS Tibial components, noting that the FDA had received 114 Medical Device Reports of loosening that required revision surgery. (*Id.* ¶¶ 17, 155–56.)

² The difference between CR–Flex and LPS–Flex knee designs is whether the patient's posterior cruciate ligament is retained. In LPS–Flex knees,

the cruciate ligament is sacrificed and replaced with a tibial post and femoral notch that perform the function of the posterior cruciate ligament. (*Id.* ¶¶ 55–56.) The Gender Solutions versions of these two products are femoral components designed specifically for women. (*Id.* ¶ 65.)

Though the Flex femoral components have not been similarly subject to a recall, Plaintiffs allege that these components are similarly prone to loosening. The Flex femoral components are “high-flex” devices, designed to accommodate flexion (bending of the knee), up to 155 degrees. (*Id.* ¶¶ 9, 62–63; Pls.’ Technical Mem. at 7–8.) While a typical, healthy knee has the capacity to bend between 155 to 160 degrees, the Zimmer NexGen non-Flex knees that preceded the Flex versions were able to achieve only between 120 to 130 degrees of flexion. (Master Compl. ¶¶ 9, 39, 57.) Plaintiffs allege that Zimmer marketed the Flex knee design for patients with more active lifestyles, particularly for those who garden or kneel for prayer, or for those whose cultural activities and lifestyles require considerable squatting or kneeling activities. (*Id.* ¶¶ 102–10.)

*2 Plaintiffs cite to a number of studies in peer-reviewed journals, however, that observe high rates of loosening for Flex femoral components. (Master Compl. ¶ 128–29; Pls.’ Technical Mem. at 11; Pls.’ Resp. at 31.)³ The studies hypothesize that the loosening is caused by asymmetric distribution of the heightened forces during deep knee flexion. See P. Bollars et al., *Femoral Component Loosening in High-Flexion Total Knee Replacement*, 93–B J. Bone & Joint Surgery 1355, 1361 (2011) (“[H]igh-flexion designs have a greater risk for loosening of the femoral component than conventional TKR designs. The absence of femoral load sharing between the prosthetic component and the condylar bone during flexion is in our opinion an important contributing factor.”); Sung–Do Cho et al., *Three- to Six-Year Follow–Up Results After High–Flexion Total Knee Arthroplasty: Can We Allow Passive Deep Knee Bending?*, 19 Knee Surgery, Sports Traumatology, *Arthroscopy* 899, 903 (2011) (“[W]ith passive deep knee bending, excessive compressive force could be applied at the posterior femoral condyle, leading to distal shear and anterior tensile forces.... Inadequate bony support of the posterior femoral condyle may result in micromotion and early loosening of the femoral component.”); H.S. Han et al., *High Incidence of Loosening of the Femoral Component in Legacy Posterior Stabilised–Flex Total Knee Replacement*, 89–B J. Bone & Joint Surgery 1457, 1460 (2007) (“If deep knee flexion is achieved, asymmetrical loading between the medial and lateral compartments of

a TKR may contribute to loosening and failure of the implant.”).⁴ Plaintiffs also question whether NexGen Flex femoral components offer any real benefit in flexion, citing studies that show no statistically significant difference in the range of motion achieved by those with Flex devices when compared with that of those implanted with their non-Flex counterparts. (Master Compl. ¶¶ 127, 131.)

³ Plaintiff also cites to a study conducted by Drs. Robert Berger and Craig Della Valle, presented at the American Association of Orthopaedic Surgeons in March 2010, in which the authors observed that out of 108 CR–Flex femoral components examined, 39 showed signs of loosening, 9 were revised for failed femoral loosening, and 1 was subject to an impending revision. (Master Compl. ¶¶ 140–41.) Dr. Berger, who was involved in the design of the NexGen Flex Knee system, was later the subject of a *New York Times* article reporting on his findings. (*Id.* ¶¶ 13, 136–37.).

⁴ The studies admit that other factors such as physician error and patient lifestyle may also contribute to loosening, and note the limitations of their methodologies. Bollar et al., *supra*, at 1361 (noting that *in vitro* laboratory testing could not replicate conditions *in vivo*, such as a patient’s lifestyle); Cho et al., *supra*, at 903 (noting limitations in a retrospective analysis of the authors’ own patients, including a lack of control group); Han et al., *supra*, at 1460 (noting the weakness in the “retrospective, non-comparative design and the relatively small number of patients”).

DISCUSSION

I. Applicability of Rule 12(b)(6)

As a preliminary matter, the parties disagree about whether Defendants are entitled to bring a motion to dismiss particular causes of action in Plaintiffs’ Master Complaint. Plaintiffs raise two objections to 12(b)(6) motion practice: (1) that Defendants waived their right to bring a motion to dismiss when, prior to the consolidation of these cases in this Multidistrict Litigation (“MDL”), the Defendants filed answers to the complaints in individual actions involving each of the devices at issue;⁵ and (2) that the Plaintiffs’ individual actions should not be subject to a “master motion

to dismiss" directed at the Master Complaint, which is merely an administrative device that Plaintiffs objected to filing in the first place. The court addresses each of these arguments in turn.

5 Cases in which Defendants filed answers prior to consolidation in this MDL include: *Teague v. Zimmer, Inc.*, No. 11 C 5727 (LPS Flex); *Singsaas v. Zimmer, Inc.*, No. 11 C 5474 (LPS Flex and MIS tibial component); *Davis v. Zimmer, Inc.*, No. 11 C 5472 (LPS Flex); *Barlow v. Zimmer, Inc.*, No. 11 C 5758 (LPS Flex); *Sizemore v. Zimmer, Inc.*, No. 11 C 5477 (CR Flex); *Sloan Perry v. Zimmer, Inc.*, No. 11 C 5725; *Mees v. Zimmer, Inc.*, No. 11 C 5724 (CR Flex); *Hayes v. Zimmer, Inc.*, No. 11 C 5716 (CR Flex); *Genslinger v. Zimmer, Inc.*, No. 11 C 5726 (CR Flex); *Cleveland v. Zimmer, Inc.*, No. 11 C 1210 (CR Flex and MIS tibial component); *Wahlman v. Zimmer, Inc.*, No. 11 C 5486 (Gender Solutions CR Flex); *Anderson v. Zimmer, Inc.*, No. 11 C 5490 (Gender Solutions LPS Flex).

A motion under Rule 12(b)(6) for failure to state a claim upon which relief may be granted "must be made before pleading if a responsive pleading is allowed." FED. R. CIV. P. 12(b). A motion for judgment on the pleadings under Rule 12(c) may be filed after pleadings are closed, however, and such a motion is governed by the same standard as a 12(b)(6) motion. See *Buchanan-Moore v. Cnty. of Milwaukee*, 570 F.3d 824, 827 (7th Cir.2009). Thus, Defendants are free to file a Rule 12(c) motion arguing that complaints failed to state a claim upon which relief can be granted. See FED. R. CIV. P. 12(h) (2)(B). The fact that Defendants have styled their motion to dismiss as a Rule 12(b)(6) motion does not alter this analysis. See *Alioto v. Town of Lisbon*, 651 F.3d 715, 718 (7th Cir.2011) (citing *McMillian v. Collection Prof'l's Inc.*, 455 F.3d 754, 757 n. 1 (7th Cir.2006)). The court concludes that it makes no difference whether Defendants' motion is a 12(b)(6) motion in response to the Master Complaint—which, as an amended complaint, supercedes the original complaint, rendering all prior pleadings without legal effect, see *Massey v. Helman*, 196 F.3d 727, 735 (7th Cir.1999)—or a motion filed after the close of pleadings under Rule 12(c).

*3 Plaintiffs' second challenge to the propriety of this motion requires more analysis. They contend that a "master motion to dismiss" targeted at the Master Complaint is inappropriate in light of the purposes of a consolidated complaint in an MDL. Plaintiffs cite a number of MDL opinions which recognize that a "master" or "consolidated" complaint is a "procedural

device used to promote judicial efficiency and economy," not to be "given the same effect as an ordinary complaint" or considered to "merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another." *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 141–42, 144 (E.D.La.2002) (quoting 9 Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2382 (1971)) (citing Diana E. Murphy, *Unified and Consolidated Complaints in Multidistrict Litigation*, 132 F.R.D. 597 (1991)); see also *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D.La.2006) ("[A] master complaint is only an administrative device used to aid efficiency and economy and, thus, should not be given the status of an ordinary complaint."); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2009 WL 2433468, at *8 (S.D.W.Va. Aug.3, 2009) (considering a motion to dismiss in light of "[t]he administrative nature of a master complaint and its focus on facilitating management of the litigation, as opposed to being a primary operative pleading"). This court agrees that "master" or "consolidated" complaints must be interpreted in light of the "primary purpose" of multidistrict litigation: "to promote efficiency through the coordination of discovery." *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL No. 1014, 1997 WL 109595, at *2 (E.D.Pa. Mar.7, 1997); see also 28 U.S.C. § 1407(a) ("[T]ransfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.").

In light of a master complaint's administrative purpose, several MDL courts have refused to entertain motions to dismiss master complaints where doing so would require case-specific rulings to determine the sufficiency of each individual plaintiff's factual allegations. See *In re Nuvaring Prods. Liab. Litig.*, No. 4:08MD1946 RWS, 2009 WL 4825170, at *2 (E.D.Mo. Dec.11, 2009); *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-1928, 2009 WL 577726, at *8 (S.D.Fla. Mar.5, 2009). In *Trasylol*, for example, the court, faced with over 400 separate cases, assessed the sufficiency of the master complaint's fraud claims with "substantial leniency"; the court concluded that any master complaint that contained all of the plaintiff-specific allegations defendant demanded would "completely remov[e] the compromise and attempt at efficiency the Parties and [the court] had in mind in allowing the filing of the Consolidated Master Complaint." *Trasylol*, 2009 WL 577726 at *8. Similarly, the *Nuvaring* court concluded that case-specific rulings on the sufficiency of the plaintiffs' allegations

*4 “are neither the purpose, nor the forte of a court presiding over a multi-district litigation. A MDL seeks to promote judicial economy and litigant efficiency by allowing the transferee court to preside over matters common among all cases.... Given this function, the transferee court typically does not rule on cumbersome, case specific legal issues.”

Nuvaring, 2009 WL 4825170, at *2 (quoting *In re Phenylpropanolamine Prods. Liab. Litig.*, No. MDL 1407, 2004 WL 2034587, at *2 (W.D.Wash. Sept.3, 2004)). The court agrees with this rationale. With more than 549 individual actions already consolidated in this litigation, the Master Complaint cannot be expected to include specific factual matter for claims that require plaintiff-specific proof. The proper court to hear dispositive motions concerning the sufficiency of plaintiff-specific allegations is the transferor court, see *Manual for Complex Litigation (Fourth)* § 22.37 (“When the MDL pretrial proceedings are concluded and individual cases are remanded to the transferor courts, the transferor judge must decide whether additional discovery and other pretrial work require completion, including deciding dispositive motions), or this court when it considers exemplar cases.

Where defendants bring a motion to dismiss that raises issues common to all plaintiffs, however, the administrative nature of a Master Complaint does not necessarily preclude 12(b) (6) motion practice. Defendants cite a number of cases where MDL courts have entertained motions to dismiss “master” or “consolidated” complaints under such circumstances. See *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1360 (11th Cir.2011) (affirming dismissal of consolidated RICO and consumer protection claims brought by insurers against drug manufacturer involving an illegal off-label marketing campaign); *In re Katrina Canal Breaches Litig.*, 309 F. App'x 836, 839 (5th Cir.2009) (affirming judgment on the pleadings dismissing a consolidated complaint brought by property owners against the port commissioners who, by statute, were not responsible for the design, construction, or maintenance of levees and floodgates); *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, No. MDL 07-1873, 2008 WL 5217594, at *1-2, 20

(E.D.La. Dec.12, 2008) (granting in part and denying in part motions to dismiss a master complaint involving breach-of-warranty claims for heightened formaldehyde levels in FEMA-supplied trailers); *In re ConAgra Peanut Butter Prods. Liab. Litig.*, No. 1:07-MD-1845-TWT, 2008 WL 2132233, at *1 (N.D.Ga. May 21, 2008) (granting in part and denying in part a consolidated complaint arising from peanut butter contaminated with salmonella); *In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liab. Litig.*, No. MDL 05-01699 CRB, 2007 WL 2028408, at *9 (N.D.Cal. July 10, 2007) (sustaining in part and dismissing in part a consolidated complaint brought by consumers against a drug manufacturer alleging a misleading marketing campaign); *In re Bridgestone/Firestone Inc., Tires Prods. Liab. Litig.*, 153 F.Supp.2d 935, 938-48 (S.D.Ind.2001) (granting a motion to dismiss state-law claims seeking recall of automobile tires as preempted by federal law). Plaintiffs do not attempt to distinguish these cases. Consequently, the court will consider Defendants' motion to dismiss to the limited extent that it challenges the sufficiency of the factual allegations common to all Plaintiffs.

II. Choice of Law

*5 In its Order concerning Defendants' contacts with prospective expert witnesses who are also treating physicians of individual Plaintiffs, this court agreed with Defendants that the filing of a consolidated, master complaint does not, absent consent of the parties, alter the choice of which state's substantive law governs the claims that originated in transferor courts outside of Illinois. In an attempt to avoid the need to analyze the sufficiency of the Master Complaint under the laws of multiple jurisdictions, Defendants purport to bring this motion against only those cases transferred from Illinois federal courts.⁶ For such cases, Defendants urge, the law of either Illinois (where the injury presumptively occurred), or Indiana (the location of Zimmer's headquarters and presumably where the devices were designed and manufactured), provide the rule of decision. Zimmer's briefs primarily focus on Illinois law, however, with only passing reference to Indiana law in footnotes.

⁶ For the same reasons that this court will not entertain motions to dismiss the Master Complaint for failure to plead plaintiff-specific facts, the court is skeptical that addressing a motion to dismiss the Master Complaint for such a limited subset of the cases consolidated in this action is an efficient use of the court's time and resources. Were Defendants'

motion to turn on peculiar features of Illinois or Indiana law, the court is hesitant to invite further motion practice on the sufficiency of Plaintiffs' Master Complaint under the laws of every other jurisdiction. Because Defendants' motion primarily challenges the sufficiency of the factual allegations under federal pleadings standards, however, and because the court ultimately concludes that Plaintiffs' factual allegations are sufficient, the court will consider Defendants' motion, limited as it is to cases from transferor courts located in Illinois.

Without making a choice-of-law determination for those cases consolidated from transferor courts located in Illinois, the court will consider the sufficiency of Plaintiff's pleadings under Illinois law.⁷ As for issues of federal law, this court applies the law of the Seventh Circuit. *See In re Sears, Roebuck & Co.*, Nos. MDL-1703, 05 C 4742, 05 C 4743, 2006 WL 1517779, at *2 n. 1 (N.D.Ill. May 24, 2006) (citing *In re Gen. Am. Life Ins. Co. Sales Practices Litig.*, 391 F.3d 907, 911 (8th Cir.2004)) ("As a general rule, when a transferee court such as this court receives a case from the MDL Panel, the transferee court applies the law of the circuit in which it is located to issues of federal law.").

⁷ Defendants contend that the relevant substantive law does not differ between Illinois and Indiana, and therefore no choice-of-law determination is required. Whether or not Defendants are correct about the relevant differences between Illinois and Indiana law, the court takes Defendants' argument to be an admission, for the purposes of this motion, that sufficiency of the Master Complaint under Rule 8 to plausibly state Illinois causes of action will also satisfy the pleading requirements for Indiana causes of action.

III. Pleading Standard

Under *Federal Rule of Civil Procedure 8(a)(2)*, a plaintiff need only provide " 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests.' " *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (alteration in original) (quoting *Conley v. Gibson*, 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)); *see also Erickson v. Pardus*, 551 U.S. 89, 93, 127 S.Ct. 2197, 167 L.Ed.2d 1081 (2009). Accordingly, under Rule 8's general notice-pleading regime, a plaintiff need not provide detailed factual

allegations. *Twombly*, 550 U.S. at 555; *see also Erickson*, 551 U.S. 89 at 93, 127 S.Ct. 2197, 167 L.Ed.2d 1081 ("Specific facts are not necessary"). When evaluating the sufficiency of a complaint, the court reads its allegations in the way most favorable to plaintiff, accepting well-pleaded allegations as true and drawing inferences in favor of the plaintiff. *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir.2011). Nothing in the Supreme Court's recent pleadings jurisprudence casts doubt on these general principles. *See Swanson v. Citibank, N.A.*, 614 F.3d 400, 404 (7th Cir.2010) ("Critically, in none of the three recent decisions—*Twombly*, *Erickson*, or *Iqbal*—did the Court cast any doubt on the validity of Rule 8 of the Federal Rules of Civil Procedure."); *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir.2009) ("Any doubt that *Twombly* had repudiated the general notice-pleading regime of Rule 8 was put to rest two weeks later, when the Court issued *Erickson*").

*6 The Court has made clear, however, that the "threadbare recitals of a cause of action's elements, supported by mere conclusory statements," are not entitled to the assumption of truth afforded a plaintiff's well-pleaded factual content. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009); *see also Twombly*, 550 U.S. at 555 ("[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do" (first alteration in original) (quoting *Papsan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986)). "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. Assuming their veracity, the court must determine whether plaintiff's well-pleaded factual allegations "plausibly give rise to an entitlement to relief." *Id.*

Although "[s]pecific facts are not necessary," *Erickson*, 551 U.S. at 93, the "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all of the complaint's allegations are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555 (citations omitted). Put another way, the complaint must present sufficient factual material to allege a claim that is "plausible on its face." *Id.* at 570. Such facial plausibility exists "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The reasonable inference must appear to flow from a plaintiff's allegations; if the allegations instead are " 'merely consistent with' a

defendant's liability," they do not satisfy the plausibility test. *Id.* (quoting *Twombly*, 550 U.S. at 557). This plausibility analysis is a "context-specific task," and it calls on the court to rely on its experience and to exercise common sense. *Id.*

The Supreme Court has been careful, however, to note that the "plausibility" requirement "does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence" supporting the plaintiff's legal claims. *Twombly*, 550 U.S. at 556; *see also Iqbal*, 556 U.S. at 678 ("The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that defendant has acted unlawfully."). As the Seventh Circuit reads these decisions,

"[p]lausibility" in this context does not imply that the district court should decide whose version to believe, or which version is more likely than not.... For cases governed only by Rule 8, it is not necessary to stack up inferences side by side and allow the case to go forward only if the plaintiff's inferences seem more compelling than the opposing inferences.

*7 *Swanson*, 614 F.3d at 404. Rather, the Seventh Circuit understands the Court to require a plaintiff to "give enough details about the subject-matter of the case to present a story that holds together." *Id.*

The Seventh Circuit has also suggested that the "required level of factual specificity rises with the complexity of the claim." *McCauley v. City of Chicago*, 671 F.3d 611, 616–17 (7th Cir. 2011); *see also Swanson*, 614 F.3d at 405 ("A more complex case ... will require more detail, both to give the opposing party notice of what the case is all about and to show how, in the plaintiff's mind at least, the dots should be connected."). This sliding scale of specificity aligns with the principal policy reason driving the Court's concern about pleading standards: in complex cases, the costs of discovery are high and "often asymmetric, ... and one way to rein them in would be to make it more difficult to earn the right to engage in discovery." *Swanson*, 614 F.3d at 405; *see also Twombly*, 550 U.S. at 557–58 ("[S]omething beyond ... mere possibility ... must be alleged, lest a plaintiff with 'a largely

groundless claim' be allowed to 'take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value.' " (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005)) (internal quotation marks omitted)).

II. Sufficiency of Pleadings

A. Design Defect

Defendants concede that Plaintiffs have sufficiently pleaded design defect claims for the MIS tibial components, which was the subject of a Class II recall. Defendants nevertheless contend that the Plaintiffs' factual allegations do not give rise to a reasonable inference that the failure of Plaintiffs' knees was the result of a design defect in the Flex femoral components. Specifically, Defendants argue that while the peer-reviewed journal articles and other sources cited by Plaintiff that report higher revisions rates for recipients of Flex femoral components may be *consistent* with a theory of design defect, they are not enough to support a reasonable inference that the failures were *caused by* defects in the design. Defendants would have this court weigh the probability that the failure of Plaintiffs' knees was the result of a defect in the design of the Flex femoral components against the probability that the failure was due to other factors, such as physician error or Plaintiffs' more active lifestyles. According to Defendants, a reasonable inference of design defect arises only if the Plaintiffs' factual allegations suggest that a design defect was more likely than any of the alternative explanations Defendants raise as affirmative defenses.

The court believes that the Defendants' approach to the "plausibility" analysis is the very type of probability requirement that the Supreme Court cautioned against in *Iqbal* and *Twombly*. The Seventh Circuit has expressly cautioned that *Twombly* does not require a district court to "stack up inferences side by side and allow the case to go forward only if the plaintiff's inferences seem more compelling than the opposing inferences." *Swanson*, 614 F.3d at 404. It is not the role of this court at the pleading stage to prejudge the case by determining whether the affirmative defenses seem more plausible than Plaintiffs' products liability theory. The proper question is whether a reasonable inference can bridge the gap between Plaintiffs' factual allegations and the legal conclusions they wish to draw, and whether discovery is likely to produce evidence that will further support that inference.

*8 This case is certainly a complex one, both in terms of the size of this MDL and the technical nature of the products involved. That said, the court does not believe the gap between the well-pleaded facts and the legal conclusion for which Plaintiffs argue is as large as in cases where the Supreme Court has found a plaintiff's pleading deficient. In the complex antitrust claims involved in *Twombly*, the Court concluded that evidence of parallel conduct amongst the "baby Bells," without more, did not support a reasonable inference that the companies had illegally conspired to avoid competing with one another. *Twombly*, 550 U.S. at 554. Likewise, in the relatively more straightforward discrimination case presented in *Iqbal*, see *Swanson*, 614 F.3d at 408 (Posner, J., dissenting) (describing *Iqbal* as "not especially complex"), the Court perceived a large gulf between the alleged mistreatment at the hands of government agents and the conclusion that officials at the highest levels of government were aware of and condoned that treatment for reasons related to the plaintiff's religion, race, or national origin. *Iqbal*, 556 U.S. at 680–83. In contrast, the gap between well-pleaded factual allegations that the Flex femoral components failed at a higher rate than non-Flex components and the conclusion that the failure is attributable to the difference in design between the two components is not so large that Plaintiffs need plead substantial additional facts to make that inference a reasonable one.

Further, the well-pleaded facts in this case make it distinguishable from cases cited by Defendants that courts have dismissed for failure to state a design defect claim. In *Frey v. Novartis Pharmaceuticals Corp.*, a plaintiff who experienced multi-organ hypersensitivity after ingesting anti-seizure medication brought a suit against the drug's manufacturer when the manufacturer later issued a label change and a warning letter to doctors adding a precaution regarding that condition as a potential side effect of the drug. 642 F.Supp.2d 787, 789–90 (S.D.Ohio 2009). While the case was allowed to proceed on a failure-to-warn theory, the court concluded that with regard to design defect, the plaintiff had "simply provided a formulaic recitation of the elements of a claim under the statute," and had "not alleged any facts that would permit the Court to conclude that there was a defect in the design or formulation of [the drug] and that the defect was the proximate cause of [the plaintiff's] alleged injuries." *Id.* at 795; see also *Tillman v. Taro Pharm. Indus. Ltd.*, No. 10-cv-04202, 2011 WL 3704762, at *4 (N.D.Ill. Aug.17, 2011) (concluding that the plaintiff's complaint included "only formulaic recitations of the elements of her cause of action").

In contrast, Plaintiffs allege that the revision rate for Flex knees is higher than for their non-Flex counterparts, and that the Flex knees do not provide a statistically significant advantage in patients' postoperative range of motion—the purported benefit of the Flex knees. Plaintiffs reference studies in peer-reviewed journals that support both of these points. That these studies note their own limitations and the possibility that other causes may explain the higher revision rates does not mean that design defect is not one of the plausible explanations.

*9 Defendants also cite a products liability case from the Eastern District of California for the proposition that "[a] sufficient factual allegation would explain how the particular design of the [product] caused [plaintiff] harm." *Altman v. HO Sports Co.*, No. 1:09-cv-1000 AWI SMS, 2009 WL 4163512, at *8 (E.D.Cal. Nov.23, 2009); see also *Goodson v. Boston Scientific Corp.*, No. 1:11-CV-3023-TWT, 2011 WL 6840593, at *4 (N.D.Ga. Dec.29, 2011) (dismissing a design defect claim because "[t]he Complaint does not describe how the ... devices were defective"). In a post-*Twombly/Iqbal* decision, however, the Seventh Circuit rejected a defendant's objection to a products liability claim brought against the manufacturer of a hip replacement system on the grounds that the complaint did not "specify the precise defect." *Bausch v. Stryker Corp.*, 630 F.3d 546, 560 (7th Cir.2010). The court recognized that "although the complaint would be stronger with such detail," failure to plead such detail did not support dismissal for failure to satisfy Rule 8 pleading requirements. *Id.*

At any rate, the court believes that Plaintiffs here have provided sufficient factual allegations concerning the nature of the defect. In the Master Complaint and in the technical report and presentation, Plaintiff cited to studies that posit that the loosening may be the result of the distribution of the load during deep flexion. Plaintiffs further cite studies that question whether the Flex devices offered a clear advantage in a patient's postoperative range of motion. These allegations give Defendants sufficient notice of the nature of the defect Plaintiffs allege. In the light most favorable to Plaintiff, these factual allegations are sufficient to support a reasonable inference that the product failed to perform as an ordinary consumer would expect and that the benefits of the design do not outweigh the inherent risk of loosening. See *Blue v. Envtl. Eng'g, Inc.*, 215 Ill.2d 78, 91–92, 293 Ill.Dec. 630, 828 N.E.2d 1128, 1138–39 (2005) (explaining Illinois's adoption of the consumerexpectation test and the risk-utility test).

B. Failure to Warn

Similar to their argument that Plaintiffs have not pleaded facts sufficient to support the inference that Plaintiffs' injuries were caused by defects in the femoral component, Defendants assert that the Master Complaint does not contain sufficient factual allegations to support a strict liability claim based on a failure-to-warn theory. Specifically, Defendants claim that the Master Complaint lacks factual allegations concerning which product labeling or information contained inadequate warnings; what those warnings should have been; whether Zimmer knew or should have known about the unwarned dangers; and how Zimmer's failure to warn proximately caused Plaintiffs' injuries, which, under the "learned intermediary" doctrine adopted by Illinois law, requires a showing that had Defendants adequately warned Plaintiffs' *physicians*, those physicians would not have chosen to implant the Flex femoral components. *See Hansen v. Baxter Healthcare Corp.*, 198 Ill.2d 420, 430, 261 Ill.Dec. 744, 764 N.E.2d 35, 42 (2002).

*10 Upon review of Plaintiffs' factual allegations, the court concludes that they do support a reasonable inference in favor of Plaintiffs' failure to warn claim. Plaintiffs offer detailed factual allegations concerning Zimmer's marketing of the Flex components: They allege that Zimmer promoted the Flex knees as safe and effective to accommodate up to 155 degrees of flexion, especially in active individuals who perform high-flexion activities such as gardening and kneeling for prayer that require deep flexion. (Master Compl. ¶¶ 102–110; Pls.' Resp. 27–29.) Plaintiffs allege, further, that Zimmer promoted the knees as safe and effective for all patients, even for those who do not have the need of higher flexion. (*Id.* ¶ 69, 261 Ill.Dec. 744, 764 N.E.2d 35.) Regardless of whether the precise representations Plaintiffs cite were directed to patients or physicians, physicians appear to have received the message: for example, the peer-reviewed studies cited by Plaintiffs, written by physicians who are presumably experts in the field, note that the NexGen components were designed to safely provide high degrees of flexion. *See Cho et al., supra*, at 902 ("The NexGen® LPS-flex total knee system was designed to provide 150° of flexion following TKA."); Han et al., *supra*, at 1457 ("The NexGen legacy posterior stabilised (LPS)-flex fixed TKR ... is designed to allow 155° of knee flexion safely.").

If, as is plausible from Plaintiffs' factual allegations, the deep flexion that the design was meant to accommodate causes loosening in the long run, Zimmer's alleged representations

would be misleading without further warnings. As for allegations that Zimmer knew or should have known of the higher risks of loosening, the court notes that even under the heightened pleading standards for fraud, a person's mental state may be alleged generally. *See Burks v. Raemisch*, 555 F.3d 592, 594 (7th Cir.2009). It is at least plausible that Zimmer was put on notice of the increased risk from the studies and reports of higher loosening rates Plaintiffs cite. Further, with respect to the issue of whether a Plaintiff's physician would have opted against using the Flex femoral components in the face of adequate warning, the type of detail Defendant seeks appears to be plaintiff-specific. For purposes of the Master Complaint, the court concludes Plaintiffs have sufficiently alleged that "proper warning would have been heeded and no health care professional, including Plaintiffs [''] physicians, would have used" the Flex femoral components. (Master Compl. ¶¶ 262, 273, 284, 295); *see also Erickson v. Baxter Healthcare, Inc.*, 151 F.Supp.2d 952, 970 (N.D.Ill.2001) (observing that even at the summary judgment state, "the plaintiffs are entitled ... to a presumption that a learned intermediary would have heeded the warning given"). Defendants' motion to dismiss the failure to warn claims in Plaintiffs' Master Complaint is denied.

C. Manufacturing Defect

*11 Defendants also contend that Plaintiffs' factual allegations are insufficient to support a plausible claim of manufacturing defect. Similar to their argument concerning design defect, Defendants assert that the Master Complaint merely offers a "formulaic recitation" of the elements of a manufacturing defect, without providing factual allegations concerning the manufacturing specifications and standards and how the product deviated from those specifications and standards. Unlike the challenges to the design defect and failure-to-warn claims, however, Defendants contest Plaintiffs' manufacturing defect claim for both the femoral and tibial components.

As opposed to design defects, where a "specific unit conforms to the intended design but the intended design itself, or its sale without adequate instructions or warnings, renders the product unreasonably dangerous," a manufacturing defect generally "occurs in only a small percentage of units in a product line." *Blue*, 215 Ill.2d at 89, 293 Ill.Dec. 630, 828 N.E.2d at 1137. The sheer number of Plaintiffs in this litigation suggests defects in the design of the components, but individual Plaintiffs may have claims for manufacturer defect as well. Consequently, the type of factual allegations Defendants assert are absent from the Master Complaint

appear to be plaintiff-specific allegations, the sufficiency of which is best left for a court considering individual plaintiffs' substantive pleadings.

Moreover, as mentioned above, the Seventh Circuit rejected a similar argument that a plaintiff had failed to specify the precise defect that caused her hip replacement to fail. *See Bausch*, 630 F.3d at 560 ("Rule 9(b) does not impose any special requirement that such a claim be pled with particularity, as it does for fraud claims, for example."). Additionally, the Seventh Circuit noted that it is common for "injured plaintiffs to plead both defective manufacture and defective design and to pursue discovery on both theories." *Id.* The court reasoned that "the victim of a genuinely defective product ... may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem." *Id.* Consequently, the most appropriate time to address whether these cases involve design defect claims or manufacturing defect claims is at summary judgment. *See id.* (collecting cases).

D. Remaining Claims

The court need address Defendants' remaining objections to the Master Complaint only briefly. Defendants' motion to dismiss the parallel negligence claims and claims for implied warranty of merchantability concerning the Flex femoral components rest on the argument, already rejected by the court, that Plaintiffs have not offered adequate factual allegations for the court to draw a reasonable inference that the Flex femoral components were defective. The remainder of Defendants' motion seeks dismissal of claims against both the Flex femoral and MIS tibial components for failure to plead plaintiff-specific facts.

*12 The perceived inadequacy of the Master Complaint's factual allegations supporting the negligent misrepresentation, express warranty, and implied warranty of fitness claims concern the absence of plaintiff-specific facts. For instance, Defendants assert that "[n]owhere does the Master Complaint identify a single statement from the array of promotional material, package inserts, and surgical technique instructions related to the Devices ... that was communicated to any *particular* Plaintiff or physician and that constitutes an actionable misrepresentation or warranty." (Zimmer's Mot. to Dismiss, In Part, Master Long Form Compl. and Jury Demand, at 27) (emphasis added). Likewise, Defendants also seek to dismiss Plaintiffs' consumer fraud claims under the Illinois Consumer Fraud Act ("ICFA"), 815 ILCS 505/1 *et seq.*, for failure to include

plaintiff-specific facts about particular misrepresentations. Unlike Plaintiffs' other claims, however, the ICFA claim is a species of fraud claim subject to the heightened pleading standard of Rule 9. *See Greenberger v. GEICO Gen. Ins. Co.*, 631 F.3d 392, 399 (7th Cir.2011). Consequently, to properly plead an ICFA claim, "a plaintiff must state the identify of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated." *ABN AMRO, Inc. v. Capital Int'l Ltd.*, 595 F.Supp.2d 805, 849 (N.D.Ill.2008).

In the *Trasylol* case mentioned above, the court addressed the pleading of fraud in an MDL master complaint. *See Trasylol*, 2009 WL 577726, at *8-9. The court concluded that particularized pleadings were not feasible in a master complaint, and instead preferred to "assess the sufficiency of plaintiffs' claims with substantial leniency, especially when the information that may or may not support Plaintiffs' claims is largely within the control of the Defendants." *Id.* at *8. The court cautioned, however, that "leniency must not overreach so as to effect a negation of the policy behind Rule 9." *Id.* at *9. While the court concluded that the plaintiffs had "minimally stated enough to allow discovery" into what the defendant knew of the safety of the drug in question, the court noted that information concerning misrepresentations lay "largely in the possession of Plaintiffs' physicians, and so, any allegation of fraud based on such statements must be pled with particularity in the individual Plaintiff's complaint, and be subject to discovery during the case-specific discovery state if, and only if, properly alleged." *Id.*

Like the *Trasylol* court, this court cannot envision a Master Complaint pleaded with the type of plaintiff-specific particularity Defendants believe is necessary. A motion to dismiss the Master Complaint is not the appropriate time to address deficiencies in plaintiff-specific allegations in the Short Form complaints or the Plaintiffs' fact sheets. For purposes of the Master Complaint, the court concludes that the factual allegations concerning the marketing and promotion of the devices are sufficient to put Defendants on notice of the types of representations Plaintiffs believe form the basis of these claims. The court considers summary judgment upon a more fully developed record the most appropriate time to address these claims. Should any Plaintiff assert reliance on a fraudulent statement made directly to them or their physician by Zimmer agents or other persons, however, the court expects the factual allegations in Plaintiffs' fact sheets to satisfy Rule 9's particularity requirement. *See Trasylol*, 2009 WL 577726, at *12.

***13** Finally, Defendants ask this court to dismiss Plaintiffs' claim for punitive damages. Defendants contend that Plaintiffs have not pleaded sufficient facts to make a plausible claim that Defendants acted "with fraud, actual malice, deliberate violence or oppression, or ... willfully, or with such gross negligence as to indicate a wanton disregard for the rights of others." "*Slovinski v. Elliot*, 237 Ill.2d 51, 58, 340 Ill.Dec. 210, 927 N.E.2d 1221, 1225 (2010) (quoting *Kelsay v. Motorola, Inc.*, 74 Ill.2d 172, 186, 23 Ill.Dec. 559, 384 N.E.2d 353, 359 (1978)). Because Plaintiffs' consumer fraud claim remains, and because Plaintiffs contend that Defendants alleged misrepresentations were not only

negligent, but reckless, the court concludes that dismissal would be premature.

CONCLUSION

For the above reasons, Defendants' Motion to Dismiss, in Part, Master Long Form Complaint and Jury Demand [258] is denied.

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TAB 32

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United States District Court, D. New Jersey.

IOWA NETWORK SERVICES, INC., Plaintiff,
v.

AT&T CORP., Defendant.

Civil Action No. 3:14-cv-3439 (PGS) (LHG)

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Signed 10/01/2019

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MEMORANDUM AND ORDER

SHERIDAN, U.S.D.J.

*1 This matter comes before the Court on a motion filed by Defendant AT&T Corp. (“AT&T”) to maintain a stay of this case pending further action by the Federal Communications Commission (“FCC”) and the D.C. Circuit. The parties’ respective briefs raise the following issues regarding the motion to maintain the stay: (1) whether a stay is permitted under the Hobbs Act, 28 U.S.C. § 2341; (2) whether the Court should continue to invoke the primary jurisdiction doctrine to continue the stay until the final outcome of the FCC proceeding; and (3) whether it would be appropriate for the Court to issue a stay pending appeal of the FCC ruling to the D.C. Circuit under *Landis v. N. Am. Co.*, 299 U.S. 248 (1936).

FACTS

Defendant AT&T is a provider of long-distance telecommunications services to all states. Plaintiff Iowa Network Services d/b/a Aureon (“INS”) provides telecommunication services known as Central Equal Access (“CEA”) services within Iowa. AT&T transports telecommunication traffic to and from local telephone

companies that serve end user customers. To transport communication traffic to end users in rural Iowa, AT&T delivers traffic to INS, then INS sends or switches the traffic to its network or the network of other local telephone companies who then, in turn, deliver the call to the end user. For INS services, INS charges AT&T a fee set forth in a tariff filed with the FCC, as discussed below.

AT&T has denied that it owes any fees to INS, and has filed counterclaims alleging that INS’s operational practices in imposing tariffed rates for CEA service violate several provisions of the Federal Communications Act (“Communications Act”), including those provisions proscribing unjust and unreasonable practices. Generally speaking, AT&T alleges that INS operated contrary to the FCC’s authorization by allegedly violating the Communications Act because, *inter alia*: (1) INS has refused to comply with certain FCC rate caps; and (2) INS has channeled most of its traffic through rural local exchanges. The critical facts underlying these two contentions are that these rural exchanges are authorized to charge higher tariff rates, and as a result, the cost of the services to AT&T substantially rises, even though INS could have more effectively routed the call through local exchanges whose rates were lower. This practice is referred to as “access stimulation.” AT&T alleges that, in order to stop access stimulation, the FCC capped such rates for those charges in 2011.

On October 14, 2015, the Court, among other things, referred this matter to the FCC pursuant to the primary jurisdiction doctrine. (See ECF No. 43). In determining whether to refer the matter to the FCC, the Court undertook an in-depth review of the facts alleged in AT&T’s counterclaims. (See *id.*; ECF No. 9). For context, some of these facts are recapitulated below.

i. ACCESS SERVICES

According to AT&T’s counterclaims, INS provides a service known as “exchange access” or more specifically, “switched access.” (Defendant’s Answer and Counterclaims (“Counterclaims”) ¶¶ 19-29, ECF No. 9). “Switched access” is offered by local exchange carriers (“LECs”) to long distance carriers (also known as interexchange carriers or “IXCs”) to complete long distance calls. (*Id.* ¶ 20). An LEC can be classified generally as an “incumbent” LEC (referred to herein as “ILEC”), which is the traditional provider of telephone services in a local exchange, or a “competitive” LEC (“CLEC”), which is a new entrant to the local telephone

2019 WL 4861438

market. (*Id.*). The LECs provide switch access services to IXCs pursuant either to tariffs or express contracts. (*Id.*) The counterclaims provide the following example of how a long distance call is completed through these carriers: On a traditional long distance call, a caller places a call from, for example, Des Moines, Iowa to a friend in, for example, Chicago, Illinois. The caller's local Iowa phone company accepts the outgoing call at a local switch that connects the caller's premises to its network, carries the call over the local network, and eventually hands off the call in or near Des Moines to the caller's selected long distance company. The long distance company (*i.e.*, the IXC) carries the call over its national network to a location near Chicago, and hands it off to a local phone company (an LEC) near Chicago that serves the called party. That Chicago LEC routes the call over its local network, including to a local "end office" switch that is directly connected to the called party's premises in Chicago, and the long distance call is completed. (*Id.* ¶ 21). In this example, the LEC that originated the call in Des Moines will assess an "originating" switch access charge on the IXC, and similar charges will be billed to the IXC for the "terminating" end of the call by the LEC in Chicago.

***2** In the most basic scenario, the IXC establishes a "direct connection" with an LEC. This type of arrangement is used in areas where the IXC and the LEC exchange a large volume of traffic. However, with smaller LECs, there may be insufficient traffic to justify a direct connection with a particular IXC's network, and the carriers may exchange traffic indirectly through another provider. (*Id.* ¶ 27). This "indirect" calling arrangement is approved by the FCC for use in Iowa and a few other states where competition for long distance services is developing. In order to successfully complete long-distance traffic through indirect exchanges, a CEA provider is utilized, and approved by the FCC. Because each remote ILEC had insufficient traffic volume to connect directly with each competing IXC, the remote ILECs cooperatively formed a CEA provider to transmit by long distance service to LEC. (*Id.* ¶ 28). The CEA provider should provide the services at a less costly rate due to economies of scale by handling larger volumes of access traffic. (*Id.*). Such CEA rates are provided by a tariff approved by the FCC.

ii. INS

INS was formed in 1987 by approximately 130 rural LECs to provide transport and other access services on behalf of the rural LECs. (*Id.* ¶ 29). INS was approved to provide CEA services and has deployed tandem switching and transport facilities in order to offer equal access to multiple competitive

IXCs at a single centralized location. (*Id.* ¶¶ 29, 32). At that time (*i.e.*, prior to the Telecommunications Act of 1996, which opened up local telephone service competition), there was only a single provider of local telephone service in a given area; there were no CLECs at that time. (*Id.* ¶ 30). Also at that time, prices for services offered by LEC were determined by "rate of return" regulation, which examined a carrier's reasonable costs and demand, and then rates were set to achieve a reasonable rate of return. (*Id.* ¶ 31).

INS offers a particular package of access services; specifically, INS offers access to a centralized telephone facility (called a "switch") in Des Moines, Iowa, and a network to transport calls across Iowa. (*Id.* ¶¶ 34-35). INS hands off the long distance calls to or from rural LECs, who use their own facilities to terminate or originate the calls placed to end user customers, and these carriers impose their own access charges on AT&T. Specifically, call routing works as follows:

[W]hen a customer of an IXC places a long distance call to a customer of one of the LECs that uses INS, the IXC carries the call over its network to INS's switch in Des Moines, and hands off the call to INS. INS then transports the call to a point on its fiber network that is close to the local facilities of the rural LEC. The rural LEC then picks up the call and transports it to the called party within its authorized local exchange.

(*Id.* ¶ 34). INS generally charges the IXC a flat, per minute rate for each call. (*Id.* ¶ 35).

iii. ACCESS STIMULATION

AT&T's counterclaims describe an alleged "scheme" referred to "access stimulation." (*Id.* ¶ 10). Under this "scheme," a remote LEC, which charges higher rates for access services under the FCC's rules, partners with a company that has less expensive rates due to its generation of a great deal of traffic through free calling services. (*Id.*) As a result of this "traffic-pumping," there is a sharp increase in the call traffic coming over the IXC to the remote LECs and a sharp increase in the fees incurred by the IXC. (*Id.* ¶ 11). As set forth in the

counterclaims, such traffic in Iowa would typically be routed over INS's transport ring. (*Id.* ¶ 10). AT&T claims that as a result of these access stimulation practices, the mix of traffic that INS carries has changed significantly. Formerly, nearly all of the traffic transported by INS involved the aggregation of small volumes for each of the ILECs connected to ENS. Presently, it is alleged that about 89% of the traffic handled by INS consists of traffic from CLECs engaged in access stimulation. (*Id.* ¶ 39).

iv. FCC PRICE CAPS

The access services provided by LECs are regulated by the FCC. In 2011, the FCC created several new rules with respect to pricing, and capped all interstate access rates that were in effect at the time. *See In the Matter of Connect Am. Fund A Nat'l Broadband Plan for Our Future Establishing Just & Reasonable Rates for Local Exch. Carriers High-Cost Universal Serv. Support Developing an Unified Intercarrier Comp. Regime Fed.-State Joint Bd. on Universal Serv. Lifeline & Link-Up Universal Serv. Reform -- Mobility Fund* ("Connect America Order"), 26 F.C.C. Rcd. 17663, ¶ 18 (2011). LECs were also required over time to reduce access rates for intrastate calls to the same level as interstate calls. The parties' briefing, as well as this memorandum, refers to these rules at "rate caps."

v. AT&T'S DISPUTE WITH INS

***3** According to AT&T, after INS filed its tariffs with rates that AT&T claims exceeded the rate caps set by FCC rules, AT&T disputed INS's charges pursuant to the billing dispute provisions in INS's tariff. (Counterclaims ¶ 54). AT&T also began withholding payment on certain charges, but continued to pay INS some of the amounts it has billed based upon AT&T's own estimate of what the lawful charges should be. (*Id.*). Nevertheless, AT&T claims that it has paid millions of dollars in charges associated with access stimulation, of which it contends should be refunded. (*Id.* ¶ 55). In sum, AT&T alleges, *inter alia*, that INS, and the Iowa LECs that engage in access stimulation, have engaged in unreasonable, anticompetitive, and unlawful practices by (1) conspiring to refuse to allow AT&T to use more efficient means to transport access stimulation traffic, such as a direct connection with the LEC; and (2) insisting that AT&T route traffic through INS. AT&T seeks damages as well as declaratory and injunctive relief. INS, on the other hand, contends that it is owed monies for the CEA service that INS has provided and billed to AT&T, but for which AT&T has not fully compensated INS. (ECF No. 1).

PROCEDURAL HISTORY

After AT&T objected to fees charged by INS and withheld payment, INS brought this action to recover monies allegedly owed. (*See id.*). As discussed above, AT&T counterclaimed that INS had violated the FCC's rate caps, was engaged in access stimulation, and had conspired to deny AT&T the ability to transport traffic via a direct connection. (ECF No. 9). After considering a motion to dismiss and motion for summary judgment filed by INS and a motion to stay filed by AT&T, the court referred the matter to the "fair and unbiased experts of the FCC." (ECF No. 43). INS's motion for reconsideration and interlocutory appeal to the Third Circuit were both denied. (ECF Nos. 44, 51).

AT&T then initiated a formal complaint proceeding with the FCC, namely, by filing a complaint raising four allegations concerning: (1) unlawful billing by INS for CEA service in connection with "access stimulation" traffic; (2) FCC rate cap and rate parity rules violations; (3) FCC access stimulation rules violations; and (4) INS's unreasonable manipulation of its rates. (*See* AT&T Moving Br. at 4, ECF No. 78).

The FCC issued its initial liability order in November 2017 ("Liability Order"), partially finding in AT&T's favor:

- (1) The FCC found INS violated rate cap and rate parity rules. The FCC held that, as a dominant carrier, INS's rates must be consistent with longstanding rate-of-return regulations and that INS was subject to traditional rules for access services, which were established in 2011.
- (2) The FCC found that INS's tariffs were not lawfully filed and directed INS to file a new lawful tariff. The FCC stated that a subsequent damages phase of the proceeding would determine the appropriate rate between 2013 and 2018.
- (3) The FCC recognized there were "a number of significant questions about INS's CEA practices and rates that deserve[d] further exploration," but denied AT&T's claims relating to INS's purported violation of FCC access stimulation rules.

(*See id.* at 4-5; *see also* ECF No. 53, Ex. 1).

INS filed a petition for reconsideration. The FCC denied the petition, but ruled that—in light of the 2013 tariff being

voided—the 2012 tariff would be deemed to have remained in effect. The FCC, however, noted that AT&T would have the opportunity in the damages phase to demonstrate that, in connection with the 2012 tariff, INS furtively employed improper accounting practices to conceal potential rate of return violations. (See ECF No. 54-1).

AT&T then petitioned for reconsideration, claiming that imposing the 2012 rate was improper. The FCC denied the petition, noting that AT&T would have the opportunity to challenge the 2012 rate at the damages phase of the proceeding. Both parties appealed various aspects of the FCC's orders. The FCC held the damages phase of the proceeding in abeyance.

Separately, the FCC directed INS to file a revised tariff within sixty days of the *Liability Order*, which it did on February 22, 2018. The FCC suspended the same, finding “substantial questions of lawfulness,” and later rejected the revised tariff because it exceeded the applicable benchmark and violated FCC affiliate transaction rules. INS’s second revised tariff was suspended and then rejected for similar reasons as the first. The FCC opened an investigation into INS’s ratemaking and accounting practices. INS was then directed to file another revised tariff filing no later than April 29, 2019.

*4 AT&T has appealed the FCC’s imposition of the 2012 tariff rate. INS has appealed the FCC’s classification of INS as a CLEC and the determination that INS’s rates were unlawful. INS has also challenged the FCC’s application of the CLEC benchmark rule in the investigation. The D.C. Circuit has consolidated these various petitions.

Concurrent to those proceedings, this Court considered a request by INS to lift the stay following the FCC’s *Liability Order* and August 1, 2018 Order on Reconsideration (“First Reconsideration Order”). (ECF No. 54). The Court denied that request and continued the stay to February 15, 2019. (ECF No. 69). Although the Court also encouraged the parties to engage in FCC-supervised mediation, those negotiations were unsuccessful. The stay imposed by this Court automatically expired on February 15, 2019. Currently pending before this Court is a motion filed by AT&T to maintain the stay of the proceedings pending the outcome of the D.C. Circuit proceeding and the damages phase of the FCC proceeding.

LEGAL STANDARD

Three distinct legal issues are presented in this motion. *First*, whether, as INS argues, maintaining a stay would violate the Hobbs Act. *Second*, whether, as AT&T argues, the Court should maintain the stay pursuant to primary jurisdiction doctrine. *Third*, whether the Court could properly exercise its inherent power to maintain the stay in this proceeding. The Court will address these legal issues in turn.

HOBBS ACT

INS argues that the Court lacks jurisdiction to issue the requested stay because the Hobbs Act confers exclusive jurisdiction to the federal courts of appeals with respect to stays of FCC orders. (INS Opp. Br. at 19-20, ECF No. 80). “The Hobbs Act provides the federal courts of appeal with ‘exclusive jurisdiction to enjoin, set aside, suspend (in whole or in part), or to determine the validity’ of FCC orders.” *Murphy v. DCI Biologicals Orlando, LLC*, 797 F.3d 1302, 1306-07 (11th Cir. 2015). “District courts may not determine the validity of FCC orders, including by refusing to enforce an FCC interpretation” *Id.* at 1306 (citation omitted). “If the Hobbs Act applies, a district court must afford FCC final orders deference and may only consider whether the alleged action violates FCC rules or regulations.” *Id.*

In particular, INS supports its position by citing *Sliwa v. Bright House Networks, LLC*, No. 216CV235FTM29MRM, 2016 WL 3901378, at *4 (M.D. Fla. July 19, 2016), which, in relevant part, held: “Staying this case because the Circuit Court *may* conclude that FCC incorrectly interpreted the TCPA is the *opposite* of affording the Final Order deference.” However, the Court finds *Sliwa* distinguishable from the present case. Specifically, in that case, the motion to stay was filed *after* the FCC issued a *final* order. *Sliwa*, 2016 WL 3901378, at *2. Here, the FCC issued an order that pertains *only* to liability. The FCC noted that a subsequent damages phase will take place after the interlocutory appeal is decided.

Indeed, our sister courts have declined to find that the Hobbs Act precludes a district court from entering a stay. *See, e.g., Sessions v. Barclays Bank Delaware*, 276 F. Supp. 3d 1349, 1351 (N.D. Ga. 2017) (citation omitted) (“Because the decision in the [D.C. Circuit] ... ‘is likely to have a substantial or controlling effect on the claims and issues’ in this case, a

stay is appropriate."); *Rajput v. Synchrony Bank*, 221 F. Supp. 3d 607, 616 (M.D. Pa. 2016).

*5 In short, the Court concludes that the Hobbs Act does not displace this Court's power to stay the proceeding, which is "incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis*, 299 U.S. at 254 (1936); *see also Ethicon v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) (citation omitted) (recognizing the district courts' "inherent power to manage their dockets and stay proceedings, including the authority to order a stay pending conclusion of a [Patent and Trademark Office] reexamination").

PRIMARY JURISDICTION

AT&T seeks an order from this Court maintaining the stay in this action until the D.C. Circuit and FCC have "completed their work." (See AT&T Moving Br. at 13-22). Specifically, AT&T's argument is premised on the doctrine of primary jurisdiction. Primary jurisdiction "is a doctrine specifically applicable to claims properly cognizable in court that contain some issue within special competence of an administrative agency." *Reiter v. Cooper*, 507 U.S. 258, 268 (1993). The doctrine "is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties." *U.S. Western Pac. R. Co.*, 352 U.S. 59, 63 (1956). "[I]t is a principle of judicial administration designed to achieve consideration between administrative agencies and the Courts." *James v. Global TelLink*, No. 13-cv-4989, 2014 WL 4425818, at *5 (D.N.J. Sep. 8, 2014). The doctrine applies "to claims properly cognizable in court that contain some issue within the special competence of an administrative agency." *Reiter*, 507 U.S. at 268. The doctrine of primary jurisdiction should be invoked where "the matter involves technical or policy considerations which are beyond the court's ordinary competence and within the agency's field of expertise." *MCI Commc'n Corp. v. Am. Telephone & Telegraph Co.*, 496 F.2d 214, 220 (3d Cir. 1974).

"The Third Circuit has stated that the doctrine applies when decision-making is divided between courts and administrative agencies [and] calls for judicial abstention in cases where protection of the integrity of a regulatory scheme dictates primary resort to the agency which administers the scheme." *Global Naps, Inc. v. Bell Atlantic-Net Jersey, Inc.*, 287 F.Supp.2d 532, 549 (D.N.J. 2003) (quotation marks omitted)

(quoting *Cheyney State Coil. Faculty v. Hifstedler*, 703 F.2d 732, 736 (3d Cir. 1983)). Ordinarily, primary jurisdiction "comes into play whenever enforcement of a claim requires the resolution of issues which under a regulatory scheme have been placed within the special competence of an administrative body." *James*, 2014 WL 4425818, at *6.

Generally, under the primary jurisdiction doctrine, the Court considers four factors in determining whether to refer a matter to an administrative agency: (1) whether the issues presented fall within the "conventional expertise" of judges; (2) whether the issues are within the agency's discretion or require the exercise of the agency's expertise; (3) whether there are any dangers of inconsistent rulings between the courts and agency; and (4) whether a prior application has been made to the agency. *See Oh v. AT&T Corp.*, 76 F. Supp. 2d 551, 557 (D.N.J. 1990). Under the circumstances at bar, the Court finds that all four of the *Oh* factors are present.

First, as the Court has already held in its October 14, 2015 referral order (ECF No. 43), many issues presented in this matter do not fall within the conventional expertise of the Court, which include, *inter alia*: (1) "access services" practices; (2) the terms within the Connect America Order; (3) the difference between CEA services and switched access service; and (4) the significance of whether INS is a rate of return carrier or a competitive local exchange carrier. *Second*, the remaining issues presented, currently before the FCC, relate to damages as a result of INS's purported liability. Specifically, the FCC will need to determine, among other things, whether the 2012 rate is a lawful rate. This issue is beyond the expertise of the Court and within the agency's discretion. *Third*, the FCC's liability order is currently on appeal. If the Court now lifts the stay and issues a ruling in this action, an appellate court could reverse and/or remand the FCC order, which could result in inconsistent rulings. The FCC's damages order could also be inconsistent with an order by this Court. Therefore, there is a high risk of inconsistent rulings between the courts and the agency. *Finally*, an application has plainly been made to the FCC, thus satisfying the fourth factor.

*6 As demonstrated above, all primary jurisdiction factors are present in this action. Therefore, the Court finds that a stay based on primary jurisdiction is warranted, particularly in view of the fact that the claims and issues before the Court are "factually and legally intertwined" with the issues "pending resolution before the FCC," as well as the D.C. Circuit. *See*

Peerless Network, Inc. v. MCI Commc'n's Servs., Inc., 917 F.3d 538, 543-44 (7th Cir. 2019).

THE COURT'S INHERENT POWER TO STAY PROCEEDINGS

Alternatively, the Court also finds that its inherent power to stay judicial proceedings justifies continuing the stay in this case. “[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.” *Landis*, 299 U.S. at 254.

A court considering a motion to stay proceedings (or, as is the case here, a motion to continue, or reimpose, a stay) “must weigh competing interests and maintain an even balance.” *Id.* at 254-55. The party seeking a stay “must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay ... will work damage to someone else.” *Id.* at 255.

Under *Landis* and its progeny, courts generally weigh a number of factors in determining whether a stay is appropriate, including:

whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party, (2) whether denial of the stay would create a clear case of hardship or inequity for the moving party; (3) whether a stay would simplify the issues and the trial of the case, and (4) whether discovery is complete and/or a trial date has been set.

Akishev v. Kapustin, 23 F. Supp. 3d 440, 446 (D.N.J. 2014) (citations and quotation marks omitted). Additional considerations also “arise depending upon the circumstances for which the movant requests a stay.” *Id.* “Where a stay is sought pending resolution of purportedly related litigation, ... courts consider whether resolution of the related litigation would substantially impact or otherwise render moot the present action.” *Id.* The Court reviews each of the above four factors below.

i. FACTOR ONE: WHETHER A STAY WILL RESULT IN PREJUDICE

INS sets forth two primary reasons why it will purportedly suffer prejudice if the stay in this matter is continued: (1) AT&T has not paid INS “the lawful rate for nearly five years ... for service provided to AT&T” (INS Opp. Br. at 25); and (2) the matter could be ongoing for a long time because: the D.C. Circuit has not yet set this matter for oral argument; after its decision, the case could be appealed to the Supreme Court; and there is also a subsequent damages proceeding before the FCC that will take place after the appeals process has concluded. (*See id.* at 25-28).

First, a determination of the lawful rate is precisely what has not yet been decided by the FCC. If the D.C. Circuit reverses the FCC, the agency will be forced to reconsider the liability determination. If the D.C. Circuit affirms the agency, it must assess damages. In either outcome, it remains unclear what the lawful rate will be. Thus, INS’s first contention actually supports a stay. *Second*, while it is true that this matter may continue for some time, “‘mere’ delay does not, without more, necessitate a finding of undue prejudice and clear tactical disadvantage.” *Nussbaum v. Diversified Consultants, Inc.*, No. CIV. 15-600, 2015 WL 5707147, at *2 (D.N.J. Sept. 28, 2015) (quoting *Akishev*, 23 F. Supp. 3d at 447). Accordingly, the Court is not persuaded by either INS’s arguments with respect to this factor.

ii. FACTOR TWO: WHETHER DENIAL OF THE STAY WOULD CREATE HARSHSHIP OR INEQUITY FOR THE MOVING PARTY

*7 INS contends that denying the stay would result in no prejudice to AT&T and, in fact, continuing the stay would permit AT&T to continue nonpayment for services rendered. (*See* INS Opp. Br. at 27-28). However, the FCC has also recognized that “substantial questions of lawfulness” surround INS’s ratemaking and accounting practices. (AT&T Moving Br. at 20). Further, the FCC’s imposition of the 2012 tariff is an issue currently on appeal in the D.C. Circuit. In light of the uncertain legal footing upon which the imposition of the 2012 tariff sits, the Court does not find that the second factor weighs in favor of either party.

iii. FACTOR THREE: WHETHER A STAY WOULD SIMPLIFY THE ISSUES AND THE TRIAL OF THE CASE

The interests of judicial economy weigh in favor of continuing the stay. As mentioned above, several petitions for appellate review have been filed and consolidated before the D.C. Circuit. The issues currently pending before the D.C. Circuit include, *inter alia*: (1) imposition of the 2012 tariff rate; (2) classification of INS as a CLEC; (3) the FCC's application of the CLEC benchmark rule. (See AT&T Moving Br. at 9). Moreover, the FCC's decision could be reversed and/or remanded, creating a risk of inconsistent results in the two cases. Additionally, the action remains pending before the FCC.

Further, the Court notes that in *Nussbaum*, relied upon by INS, the court considered whether to stay pending the outcome of an ancillary case in which the defendant was an intervenor. With respect to the third factor, the court held: "Given that many of the relevant issues in the case before this Court fall outside the ambit of [the matter on appeal], the resolution of [that matter] seems unlikely to significantly simplify the issues before this Court or to substantially impact the outcome of the litigation." *Nussbaum*, 2015 WL 5707147, at *3. By contrast, here, the issues on appeal are substantially similar to those at issue in this case. The third factor therefore weighs strongly in favor of granting the motion.

iv. FACTOR FOUR: WHETHER DISCOVERY IS COMPLETE AND/OR A TRIAL DATE HAS BEEN SET

This matter has been on the Court's docket since 2014. However, while the parties may have engaged in discovery before the FCC (see INS Opp. Br. at 33), it appears that no significant amount of discovery has taken place in this action pending in this Court. INS filed a motion for summary judgment on AT&T's counterclaims before its motion to dismiss was decided. The matter has been stayed since this Court's October 14, 2015 order, which also denied the motion

to dismiss and the motion for summary judgment. Most of the documents that have been filed since that order relate to the Court lifting the stay. Therefore, although the case has been pending for a while, this factor weighs in favor of continuing the stay.

Based on this analysis, the Court finds that a stay is warranted based on the Court's inherent power to stay proceedings, in addition to the primary jurisdiction doctrine.

ORDER

This matter comes before the Court on a motion filed by AT&T to maintain the stay of this action pending the outcome of an appeal to the D.C. Circuit of an FCC proceeding involving substantially similar legal issues; and to also stay pending the FCC's consideration of the matter after the conclusion of the D.C. Circuit appeal. The Court held oral argument on this matter on April 9, 2019. Accordingly, for the reasons stated herein and for good cause shown;

IT IS on this 1 day of October, 2019;

ORDERED that AT&T's motion to stay (ECF No. 78) is granted in part; and it is further

ORDERED that this matter is stayed pending the outcome of the proceedings before the D.C. Circuit; and it is further

***8 ORDERED** that either party may move to further stay the proceedings after this matter is decided by the D.C. Circuit.

All Citations

Slip Copy, 2019 WL 4861438

TAB 33

2011 WL 198026

2011 WL 198026

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Tenisha JAMES, individually and on behalf of all others similarly situated, Plaintiffs,

v.

JOHNSON & JOHNSON CONSUMER COMPANIES, INC., Defendants.

Civil No. 10-cv-03049 (DMC)(JAD).

Jan. 20, 2011.

Attorneys and Law Firms

Scott M. Lempert, Sandals & Associates, P.C., Philadelphia, PA, for Plaintiff.

Daniel B. Carroll, Drinker, Biddle & Reath, LLP, Florham Park, NJ, for Defendant.

OPINION

DENNIS M. CAVANAUGH, District Judge.

*1 This matter comes before the Court upon motion by Johnson & Johnson Consumer Companies, Inc. (“Defendant”) to dismiss the Plaintiff’s Consolidated Amended Class Action Complaint (“CACAC”) pursuant to Fed.R.Civ.P. 12(b)(1) for lack of subject matter jurisdiction. Pursuant to Fed. R. Civ. Pro 78, no oral argument was heard. After considering the submissions of the parties, and based upon the following, Defendants motion is **granted**.

I. BACKGROUND

The ten plaintiffs joined in this Complaint allege that Defendant J & J violated the FDA’s ban on methylene chloride as an ingredient in cosmetic products, pursuant to 21 C.F.R. § 700.19. Attorney for Plaintiffs previously brought six virtually identical cases before this Court, four of which were dismissed on August 2, 2010 for lack of standing pursuant to a motion for reconsideration filed by Defendant Johnson & Johnson.¹ The CACAC allegedly raises new factual and legal issues that distinguish this Complaint from the others that were dismissed by this Court, including allegations that

Johnson & Johnson has been investigated by the FDA, and that methyl chloride is an ingredient in its baby shampoo.

1

Vercellino v. Gerber Products Co. et al., Case 2:09-cv-02905 DMC-MF, CLOSED 8/2/10; *Crouch v. Johnson and Johnson Consumer Cos., Inc. et al.*, Case 2:09-cv-02905 DMC-MF, CLOSED 8/2/10; *Levinson v. Johnson & Johnson Consumer Cos., Inc. et al.*, Case 2:09-cv-03317 DMC-MF, CLOSED 8/2/10; *Boyd v. Johnson & Johnson Consumer Cos. Inc.*, Case 2:09-cv-03135 DMC-MF; CLOSED 8/2/10.

II. LEGAL STANDARD

As the Supreme Court has long held, “Constitutional standing requires (1) injury-in-fact, which is an invasion of a legally protected interest that is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; (2) a causal connection between the injury and the conduct complained of; and (3) it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). Moreover, a “legally and judicially cognizable” injury-in-fact must be “distinct and palpable,” not “abstract or conjectural or hypothetical.” *Raines v. Byrd*, 521 U.S. 811, 819, 117 S.Ct. 2312, 138 L.Ed.2d 849 (1997); *Allen v. Wright*, 468 U.S. 737, 751, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984) (internal quotations omitted) (quoting *Warth v. Seldin*, 422 U.S. 490, 498, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975), and *Los Angeles v. Lyons*, 461 U.S. 95, 101–02, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983)). As the Third Circuit has held, “while it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms.” See *Danvers Motor Co., Inc. v. Ford Motor Co.* 432 F.3d 286, 291 (C.A.3 (N.J.), 2005).

“There is a fundamental difference of review under Fed.R.Civ.P. 12(b)(1), where the existence of disputed facts will not preclude the Court from evaluating the merits of the jurisdictional claim, and Fed.R.Civ.P. 12(b)(6) where the Court is required to accept as true all the allegations of the complaint and all inferences arising from them.” *Anjelino v. New York*, 200 F.3d 73, 87 (Dd Cir., 1999). “[T]he threshold to withstand a motion to dismiss under [Rule] 12(b)(1) is thus lower than that required to withstand a Rule 12(b)(6) motion.” *Kehr Packages, Inc. V. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir., 1991).

III. DISCUSSION

*2 The Court accepts Plaintiff's contention that economic injury is sufficient to confer Article III standing such that the Court has subject matter jurisdiction over this case. The Court notes the language of *Danvers Motor Co., Inc. v. Ford Motor Co.* 432 F.3d 286, 293 (C.A.3 (N.J.), 2005) in which the Third Circuit held that "monetary harm is a classic form of injury-in-fact," and that "injury-in-fact is not Mount Everest." In spite of that language, however, Plaintiffs cannot clear the threshold requirement for showing economic injury. As the Court understands the CACAC, the economic injury for which Plaintiffs seeks redress is the price Plaintiffs paid for shampoo, which they then apparently used in bathing their children, without adverse health reactions. Whatever injury they claim to have suffered due to their subsequent discovery of methyl chloride in the shampoo could not, therefore, have been economic.² Simply put, Plaintiffs bought and used shampoo, and subsequently wished that they had not done so because they feared for the future safety of their children. Their assertion that because the product was tainted, the injury occurred at the moment of purchase, is unavailing. Plaintiff's reasoning in the CACAC is circular and unpersuasive as to the contention that Plaintiffs suffered an injury-in-fact. The CACAC avers that "had Plaintiffs known the true nature of Defendant's baby shampoo, they neither would have purchased it nor allowed their children to be exposed to it." This is undoubtedly correct, but the conclusion that "consequently, Plaintiffs have been economically damaged" simply does not follow. (See ECF Doc. 27, page ID# 483). Presumably, had Plaintiffs known about the alleged toxicity of the shampoo prior to using the product they would either have returned it unopened, or not purchased it in the first place. Once the product had been consumed, however, there was no economic injury for Plaintiffs to complain of, and the fear of future injury is legally insufficient to confer standing. Plaintiffs received the benefit of their bargain so long as there were no adverse health consequences, and the product worked as intended, meaning that the hair of Plaintiff's children was cleansed, and their eyes and skin were not irritated. There is nothing in the CACAC to suggest otherwise. The Court finds that the facts as pled in the CACAC are legally

insufficient to demonstrate an injury-in-fact of even the most *de minimis* amount, and that no further restyling of the CACAC could overcome this jurisdictional hurdle. It would be both foolish and impossible to parse and measure the amount of shampoo each Plaintiff used prior to the discovery of taint, and the Court will not entertain such a fractionated analysis. Short of seeking redress for the unused portion of a bottle of shampoo that was discarded subsequent to discovery of the alleged contamination, a practical and legal absurdity, there is simply no cognizable economic injury. The Court need not reach the issue on which the previous four cases were dismissed, namely the contention that methyl chloride was not an "ingredient" as that term is understood by the Food and Drug Administration, although the Court notes that Plaintiff's syllogistic reasoning, that methyl chloride was a "component," and therefore an "ingredient" is neither a factual nor a legal improvement over Plaintiff's previous allegations. To the extent that there is no injury-in-fact, either economic or otherwise, the "per se" adulteration of the product is simply irrelevant to these Plaintiffs, since they have no standing to bring the claim before this Court. Plaintiff should consider this issue to have been fully litigated and thus precluded for future consideration by the Court.

2

It should be noted that Plaintiffs have not alleged economic injury on a theory that they paid a premium price for this brand of shampoo based on Johnson & Johnson's misrepresentation of their product as being safe and non-toxic for children, more so than comparable but less expensive alternatives. See *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2d Cir., 2003).

III. CONCLUSION

*3 For the reasons contained herein, Defendant's motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(1) is granted. An appropriate order follows this opinion.

All Citations

Not Reported in F.Supp.2d, 2011 WL 198026

TAB 34

 KeyCite Yellow Flag - Negative Treatment
Declined to Follow by [City of Greenville, Ill. v. Syngenta Crop Protection, Inc.](#), S.D.Ill., November 18, 2010

374 Fed.Appx. 257

This case was not selected for publication in West's Federal Reporter.

See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also U.S.Ct. of Appeals 3rd Cir. App. I, IOP 5.1, 5.3, and 5.7.
United States Court of Appeals,
Third Circuit.

Ruth KORONTHALY, individually and on behalf of all others similarly situated, Appellant

v.

L'OREAL USA, INC., a New York Corporation; The Procter and Gamble Distributing LLC, an Ohio Corporation.

No. 08-4625.

|

Argued Nov. 10, 2009.

|

Opinion Filed: March 26, 2010.

Synopsis

Background: Purchaser of lipstick products containing lead brought class action against companies that manufactured, marketed, and distributed the products. Defendants filed motions to dismiss. The United States District Court for the District of New Jersey, [Dennis M. Cavanaugh, J.](#), 2008 WL 2938045, granted the motions and subsequently denied plaintiff's motions for reconsideration and to file a second amended complaint. Plaintiff appealed.

Holdings: The Court of Appeals, [Roth](#), Circuit Judge, held that:

[1] plaintiff's subjective allegation that the trace amounts of lead in the lipsticks were unacceptable to her was not an injury-in-fact sufficient to confer constitutional standing, and

[2] to the extent plaintiff contended that she lost the "benefit of the bargain" in purchasing the lipsticks, she did not demonstrate a concrete injury-in-fact.

Affirmed.

Procedural Posture(s): On Appeal; Motion to Dismiss.

West Headnotes (2)

[1] **Products Liability**  Nature of Injury or Damage

Products Liability  Persons Entitled to Sue

Products Liability  Cosmetics, soaps, and hair-care products

Subjective allegation made by purchaser of lipstick products containing lead, that the trace amounts of lead in the lipsticks were unacceptable to her, was not an injury-in-fact sufficient to confer constitutional standing; purchaser's argument that she was misled into purchasing unsafe lipstick products was belied by Food and Drug Administration (FDA) report finding that lead levels in manufacturers' lipsticks were not dangerous and therefore did not require warnings, and purchaser conceded that she had suffered no adverse health effects from using the lipsticks. [Fed.Rules Civ.Proc.Rule 12\(b\)\(1\), 28 U.S.C.A.](#)

[16 Cases that cite this headnote](#)

[2] **Sales**  Standing

To the extent purchaser of lipstick products containing lead contended that she lost the "benefit of the bargain" in purchasing the lipsticks, she did not demonstrate a concrete injury-in-fact, as required for standing; because her purchases were not made pursuant to a contract, she could not have been denied the benefit of any bargain, and purchaser did not allege that she received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably have expected. [Fed.Rules Civ.Proc.Rule 12\(b\)\(1\), 28 U.S.C.A.](#)

[31 Cases that cite this headnote](#)

*258 On Appeal from the United States District Court for the District of New Jersey (District Court No. 2-07-cv-05588), District Judge: [Dennis M. Cavanaugh](#).

Attorneys and Law Firms

[Philip A. Tortoreti](#), Esquire, [Daniel R. Lapinski](#), Esquire (Argued), Wilentz, Golman & Spitzer, P.A., Woodbridge, NJ, for Appellant Ruth Koronthaly.

[Scott L. Haworth](#), Esquire (Argued), [Nora Coleman](#), Esquire, Sedgwick, Detert, Moran & Arnold, New York, NY, [Anthony J. Anscombe](#), Esquire, Sedgwick, Detert, Moran & Arnold, LLP, Chicago, IL, [James H. Keale](#), Esquire, Sedgwick, Detert, Moran & Arnold, LLP, Newark, NJ, for Appellee L'Oreal USA, Inc.

[Michael R. McDonald](#), Esquire (Argued), [Damian V. Santomauro](#), Esquire, Gibbons, P.C., Newark, NJ, for Appellee The Procter & Gamble Distributing, LLC.

Before: [AMBRO](#), [GARTH](#), and [ROTH](#), Circuit Judges.

OPINION

[ROTH](#), Circuit Judge:

**1 Ruth Koronthaly appeals from the District Court's order granting defendant Procter & Gamble Company's ("P & G") motion to dismiss pursuant to [Federal Rule of Civil Procedure 12\(b\)\(1\)](#) for lack of standing and defendant L'Oreal USA, Inc.'s ("L'Oreal") motion to dismiss pursuant to [Rule 12\(b\)\(6\)](#). We exercise plenary review over a grant of a motion to dismiss for lack of standing and review the factual elements underlying the standing determination for clear error. [Goode v. City of Phila.](#), 539 F.3d 311, 316 (3d Cir.2008). The burden of proving each standing element rests with the plaintiff. [Danvers Motor Co., Inc. v. Ford Motor Co.](#), 432 F.3d 286, 291 (3d Cir.2005). We assume the parties' familiarity with the factual and procedural history, which we describe only as necessary to explain our decision. We will affirm the District Court's order.

Koronthaly purchased lipstick products manufactured, marketed, and distributed by appellees L'Oreal, and P & G. These lipstick products contain lead. The FDA does not regulate the presence of lead in lipstick, but Koronthaly asserts that the lipstick contains lead in far greater amounts

than permitted in candy by the FDA. Neither the packaging nor the products themselves contained any indication that the lipstick contained any lead.

Koronthaly did not know when she purchased the products that they contained any lead, and when she learned of the lead content she immediately stopped using them. Moreover, had she known of the lead she would not have purchased the products.

In November 2007, Koronthaly filed a class action complaint in the District Court for the District of New Jersey. She invoked the District Court's jurisdiction under the Class Action Fairness Act, [28 U.S.C. § 1332\(d\)\(2\)](#). After it was amended in March 2008, her complaint asserted claims for: (1) violation of the New Jersey Consumer Fraud Act, [N.J.S.A. § 56:8-1 et seq.](#); (2) breach of implied warranty under the New Jersey UCC; (3) breach of implied warranty under the Magnuson-Moss Warranty Act, [15 U.S.C. § 2310\(d\)\(1\)](#); (4) strict liability; (5) negligence per se; (6) unjust enrichment; and (7) injunctive relief.

*259 L'Oreal and P & G filed motions to dismiss pursuant to [Fed.R.Civ.P. 12\(b\)\(6\)](#) and [12\(b\)\(1\)](#), respectively. On July 25, 2008, the District Court granted those motions, finding that Koronthaly lacked standing to pursue the action. On October 24, 2008, the District Court denied Koronthaly's motion for reconsideration, and her motion for leave to file a second amended complaint. Koronthaly then filed a timely notice of appeal.

To prove constitutional standing, Koronthaly must demonstrate (1) an injury-in-fact that is actual or imminent and concrete and particularized, not conjectural or hypothetical, (2) that is fairly traceable to the defendant's challenged conduct, and (3) is likely to be redressed by a favorable judicial decision. [Summers v. Earth Island Inst.](#), — U.S. —, 129 S.Ct. 1142, 1149, 173 L.Ed.2d 1 (2009). In this case, standing founders on the first requirement, injury-in-fact.

**2 [1] Koronthaly's argument that she was misled into purchasing unsafe lipstick products is belied by the FDA's report finding that the lead levels in the Defendants' lipsticks were not dangerous and therefore did not require warnings. Moreover, Koronthaly concedes that she has suffered no adverse health effects from using the lipsticks. Koronthaly therefore has asserted only a subjective allegation that the trace amounts of lead in the lipsticks are unacceptable to her,

not an injury-in-fact sufficient to confer Article III standing. See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992) (injury-in-fact must be accompanied by “continuing, present adverse effects”) (citation omitted); *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 636 (3d Cir.1996) (Wellford, J., concurring) (“Fear and apprehension about a possible future physical or medical consequence ... is not enough to establish an injury *in fact*.”).

[2] Furthermore, to the extent that Koronthaly contends that the injury-in-fact was the loss of her “benefit of the bargain,” she mistakenly relies on contract law. See *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319–21 (5th Cir.2002) (plaintiff, whose only claim was that she “would like her money back” for having purchased a product that failed to

make certain disclosures and allegedly was defective, did not have an injury-in-fact sufficient to create standing). Her lipstick purchases were not made pursuant to a contract, and therefore she could not have been denied the benefit of any bargain. Absent any allegation that she received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect, Koronthaly has not demonstrated a concrete injury-in-fact.

For the foregoing reasons, we will affirm the order of the District Court granting the Defendants' motions to dismiss.

All Citations

374 Fed.Appx. 257, 2010 WL 1169958

End of Document

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TAB 35

 KeyCite Yellow Flag - Negative Treatment
Distinguished by [Cline v. Advanced Neuromodulation Systems, Inc.](#), N.D.Ga., June 15, 2012

2011 WL 3652311

Only the Westlaw citation is currently available.

United States District Court,
N.D. Georgia,
Atlanta Division.

Karneshiha LEONARD, Individually, and
as Administrator of the Estate of Lorenzo
Leonard, Deceased, Christopher Leonard,
Yolanda Wilson, as Legal Guardian of Shakiya
Ricks, and Jushonda Ricks, Plaintiffs,

v.

MEDTRONIC, INC., Defendant.

Civil Action No. 1:10-CV-03787-JEC.

Aug. 19, 2011.

Attorneys and Law Firms

[Romero T. Pearson](#), Pearson Law Group, Lawrenceville, GA, for Plaintiffs.

[Lori Gail Cohen](#), Greenberg Traurig, Atlanta, GA, for Defendant.

ORDER and OPINION

JULIE E. CARNES, Chief Judge.

***1** Before the Court is defendant's Motion to Dismiss [5] this case pursuant to [Rule 12\(b\)\(6\) of the Federal Rules of Civil Procedure](#). Upon review of the parties' arguments and the record, determines that defendant's motion is meritorious. Nevertheless, given the plaintiffs' request to amend their complaint, the Court **DENIES without prejudice** defendant's motion [5].

BACKGROUND

The facts, viewed in the light most favorable to Plaintiffs, are as follows. Plaintiffs are heirs of Lorenzo Leonard ("Leonard"), who is deceased. (Plaintiffs' Complaint [1] at ¶ 5.) Defendant Medtronic, Inc. manufactures and sells

implantable cardiac **defibrillators** ("ICDs").¹ (*Id.* at ¶ 2.) On February 14, 2003, Leonard was implanted with Medtronic's Marquis VR, Model 7230 ICD ("Marquis 7230 ICD"). (*Id.* at ¶ 5.) In February 2005, Medtronic recalled four ICD models, including the model Leonard had, because of a potential battery shorting problem which could cause the device to fail or malfunction. (*Id.* at ¶¶ 54, 57–58.) On November 17, 2007, Leonard was admitted to The Medical Center in Columbus, Georgia. (*Id.* at ¶ 78.) Leonard stated he had felt a spasm and chest pain, and that his ICD "went off" for the first time. (*Id.*) Leonard's ICD fired three times. (*Id.*) On November 20, 2007, while Leonard was still in the hospital, Medtronic reviewed and adjusted his ICD but did not tell him that his device had been recalled. (*Id.*)

¹ "ICDs are implantable, silver-dollar size, highly-technical electronic devices designed to detect, and almost-instantaneously treat, ventricular tachycardia, or fibrillation, a life-threatening condition. A properly functioning ICD administers an electrical pulse which reestablishes a regular heartbeat." [Clark v. Medtronic, Inc.](#), 572 F.Supp.2d 1090, 1091 (D.Minn.2008).

Plaintiffs filed this action against Medtronic on November 17, 2010. The complaint raises eight common law claims under Georgia law: (1) negligence; (2) strict liability for a design and manufacturing defect; (3) negligence per se; (4) strict liability for failure to warn; (5) breach of implied warranty; (6) breach of express warranty; (7) misrepresentation by omission; and (8) unjust enrichment.

Medtronic has filed a motion to dismiss the complaint pursuant to [FED. R. CIV. P. 12\(b\)\(6\)](#). Medtronic asserts three grounds for dismissal: (1) the complaint is inadequately pled; (2) the claims are untimely under Georgia's two-year statute of limitations; and (3) the claims are preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") under [21 U.S.C. § 360k\(a\)](#), as interpreted by the Supreme Court in [Riegel v. Medtronic, Inc.](#), 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008). The Court will discuss each ground in turn.

DISCUSSION

I. Adequacy of Complaint

A proper pleading requires a "short and plain statement of the claim showing that the pleader is entitled to relief." [FED. R.](#)

CIV. P. 8(a)(2). A pleading that fails “to state a claim upon which relief can be granted” is subject to dismissal under Rule 12(b)(6). FED. R. CIV. P. 12(b)(6). The amount of facts necessary to defeat a motion to dismiss must be enough to make the claim “plausible on its face.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).²

A claim is facially plausible if the court can draw a reasonable inference from the factual allegations that the defendant is liable for the alleged wrongdoing. *Ashcroft v. Iqbal*, —U.S. —, —, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). A claim is not facially plausible if it shows only “a sheer possibility that a defendant has acted unlawfully.” *Id.* Although a court must accept the complaint’s factual allegations as true, this tenet does not apply to legal conclusions. *Id.* The Supreme Court has incorporated these principles into a two-step process when analyzing a motion to dismiss: “1) eliminate any allegations in the complaint that are merely legal conclusions; and 2) where there are well-pleaded factual allegations, ‘assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.’” *Am. Dental Ass’n v. Cigna Corp.*, 605 F.3d 1283, 1290 (11th Cir.2010) (quoting *Iqbal*, 129 S.Ct. at 1950).

² Plaintiffs mistakenly argue that “[a] complaint should not be dismissed for failure to state a claim unless the plaintiff can prove no set of facts entitling him to relief.” (Pls.’ Resp. to Def.’s Mot. to Dismiss [9] at 4.) *Twombly* retired the “no set of facts” test previously used by the Supreme Court, referring to it as “an incomplete, negative gloss on an accepted pleading standard.” *Id.* at 562–63; *Speaker v. U.S. Dep’t of Health and Human Servs. Ctrs. for Disease Control and Prevention*, 623 F.3d 1371, 1380 (11th Cir.2010).

*2 Applying this approach, the Court may disregard most of plaintiffs’ allegations in the complaint as unsubstantiated legal conclusions. For example, plaintiffs allege in Count One that “[d]efendant carelessly manufactured, marketed, distributed, and sold” defective ICDs, and that Defendant negligently used a manufacturing process that “did not satisfy the Food and Drug Administration’s Pre–Market Approval standards for the devices.” (Pls.’ Compl. [1] at ¶¶ 71–72). This count does not specify any particular federal standard the manufacturing process violated or state how Medtronic violated that standard. Further, plaintiffs fail to allege any facts linking Medtronic’s alleged violations of the premarket approval standards to Leonard’s injuries. Plaintiffs mention earlier in their complaint that the ICD at issue was recalled

because of a battery shorting problem, but plaintiffs never allege that Leonard’s ICD battery malfunctioned or that a battery failure caused his injuries. Thus, they fail to plead any facts that would lead the Court to infer plausibly that Medtronic’s alleged noncompliance with the FDA premarket approval standards caused Leonard harm.

The rest of plaintiffs’ claims similarly suffer from a lack of well-pleaded facts. In Count Two, plaintiffs re-allege that Medtronic manufactured an unreasonably dangerous product for which it is strictly liable. In Count Three, plaintiffs assert that Medtronic was negligent per se for violating the adulteration and misbranding provisions of the FDCA. In Count Four, plaintiffs claim Medtronic failed to provide timely and adequate warnings about the manufacturing and design defects. In Counts Five and Six, plaintiffs allege that Medtronic breached an implied and express warranty that its products are safe and fit for their intended use. In Count Seven, plaintiffs state that Medtronic misrepresented the ICD’s mechanical soundness and reliability by concealing its known defects from the public. In Count Eight, plaintiffs allege that Medtronic unjustly benefitted from Leonard’s payment for an ICD that was not safe or medically effective.

All of these allegations are nothing more than “naked assertions devoid of further factual enhancement.” *Iqbal*, 129 S.Ct. at 1949 (quotation marks and citation omitted). As part of their formulaic recitation of the causes of action, plaintiffs conclude Counts One through Seven with the bare allegation that Leonard suffered injuries and died as “a direct and proximate result of Defendant’s conduct.” (Pls.’ Compl. [1] at ¶¶ 76, 84, 89, 95, 101, 107, 114.) However, as the Supreme Court has instructed, Rule 8(a) “demands more than an unadorned, the-defendant-unlawfullyharmed-me accusation.” *Iqbal*, 129 S.Ct. at 1949.

Once the complaint’s conclusory statements and formulaic recitations are excluded, the terse factual allegations contained in the complaint do not satisfy Supreme Court standards. The only facts mentioned about Leonard are that he was implanted with a Medtronic ICD in February 2003 and he experienced chest pain in November 2007, at which time his ICD fired three times and was reviewed and adjusted by Medtronic. There is no allegation that the ICD improperly fired during the November 2007 incident or that the ICD injured Leonard at that time. In fact, the complaint never alleges that Leonard’s ICD malfunctioned at any time. Although the complaint alleges that Leonard died as a result of Medtronic’s conduct, the complaint fails

to disclose when Leonard died, why he died, or how his death in any way relates to his ICD or Medtronic's actions. Even accepting plaintiffs' factual allegations as true, the Court cannot plausibly infer that Medtronic is liable for the alleged misconduct. *See id. at 1952* (concluding the complaint required more factual content in order to transform the claim " 'from conceivable to plausible' "); *Twombly*, 550 U.S. at 555 (explaining that while a complaint "does not need detailed factual allegations," the allegations "must be enough to raise a right to relief above the speculative level").

*3 In plaintiffs' response to Medtronic's motion to dismiss, they allege for the first time that Leonard suffered pain on November 30, 2008 when his ICD constantly misfired, causing his heart to respond in a *tachycardia*, and that he died that same day after going into *cardiac arrest*. (Pls.' Resp. to Def.'s Mot. to Dismiss [9] at 5.) Plaintiffs assert, without specific citation to the complaint, that the complaint makes these allegations. But these allegations appear nowhere in the complaint. As pled, none of their claims pass muster as they all fail to state a plausible claim for relief under Rule 8(a). *See Twombly*, 550 U.S. at 555, 570; *Iqbal*, 129 S.Ct. at 1949. Accordingly, all of plaintiffs' claims are due to be dismissed.

II. Timeliness of Complaint

As this case is a diversity action, the Court must apply Georgia's statute of limitations to determine whether the complaint is timely. *See Cambridge Mut. Fire Ins. Co. v. City of Claxton*, 720 F.2d 1230, 1232 (11th Cir.1983) ("[S]tate statutes of limitations are substantive laws and must be followed by federal courts in diversity actions."). Georgia law requires that "[a]ctions for injuries to the person shall be brought within two years after the right of action accrues" O.C.G.A. § 9-3-33; *see also Smith, Miller and Patch v. Lorentzson*, 254 Ga. 111, 112, 327 S.E.2d 221 (1985) (applying O.C.G.A. § 9-3-33 to products liability claims based on personal injuries); *Daniel v. Am. Optical Corp.*, 251 Ga. 166, 167, 304 S.E.2d 383 (1983) (holding that O.C.G.A. § 9-3-33 applies to personal injury actions brought under theories of strict liability and negligence). A cause of action accrues "when the plaintiff could first have maintained his or her action to a successful result." *Colormatch Exteriors, Inc. v. Hickey*, 275 Ga. 249, 251, 569 S.E.2d 495 (2002) (brackets, quotation marks, and citation omitted).

Medtronic argues that the complaint is untimely because the latest date specified in the complaint is in November 2007, three years before the complaint was filed in November 2010. Plaintiffs respond that their complaint was filed on November

17, 2010, which is less than two years after Leonard died on November 30, 2008. Although the Court must construe all factual allegations in the complaint as true on a motion to dismiss, *see Iqbal*, 129 S.Ct. at 1949, the date of Leonard's death is not alleged in the complaint itself. Accordingly, as currently pled, the action is untimely because the latest event asserted therein occurred more than two years before the complaint was filed.

III. Preemption

Medtronic's final argument in its motion to dismiss is that all of Plaintiffs' claims are preempted by the MDA. Plaintiffs respond that they have asserted parallel claims which are not subject to preemption.

A. Statutory Framework

Since 1976, the MDA, which are amendments to the Food and Drug Act, has subjected medical devices to detailed federal oversight. *Riegel*, 552 U.S. at 316. As a Class III device, the Marquis 7230 ICD falls into the most strictly regulated category.³ *Blunt v. Medtronic, Inc.*, 315 Wis.2d 612, 618, 760 N.W.2d 396 (2009). New Class III devices must undergo a "rigorous" premarket approval process by the FDA. *Riegel*, 552 U.S. at 317 (quotation marks and citation omitted). This process typically involves a multivolume application by the manufacturer, which includes reports of all studies about the device's safety and effectiveness as well as a full description of the manufacturing process. *Id.* at 317-18. "The FDA spends an average of 1,200 hours reviewing each application." *Id.* at 318. After weighing the risks and benefits of the device, the FDA may grant premarket approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* (citing 21 U.S.C. § 360e(d)).

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A Class III device is " 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.' " *Riegel*, 552 U.S. at 317 (citing 21 U.S.C. § 360c(a)(1)(C) (ii)).

*4 Following premarket approval, the FDA continues to oversee the medical device. *Id.* at 319. A manufacturer is prohibited from changing the design, manufacturing process, label, or any other attribute that would affect the device's safety or effectiveness, unless the FDA grants supplemental premarket approval. *Id.* (citing 21 U.S.C. § 360e(d)(6)(A)(I)).

Additionally, the manufacturer must report to the FDA any new investigations or studies it knows of about the device and any incidents connecting the device to death or serious injury. *Id.* The FDA “must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.” *Id.* at 319–20.

The MDA contains the following express preemption clause:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

[21 U.S.C. § 360k\(a\)](#). The exception noted in subsection (b) allows exemption of some state and local requirements from preemption. *Riegel*, 552 U.S. at 316.

Riegel established a two-part test for determining if a state-law claim is preempted under [§ 360k \(a\)](#). *Id.* at 321–22. A court must first determine whether there are federal law requirements that apply to the device at issue. *Id.* at 321. In *Riegel*, the Supreme Court held that FDA premarket approval for a particular device imposes federal “requirements” for purposes of [§ 360k](#). *Id.* at 322–23. Here, Plaintiffs do not contest that the premarket approval for Leonard’s ICD imposes federal requirements for that device and therefore satisfies the first prong of *Riegel*’s preemption test. *See id.*; *see also Wolicki–Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1297–98, 1301 (11th Cir.2011) (finding that a Class III pump system’s premarket approval “imposes specific requirements on it that are sufficient to preempt a state law claim”).

Next, a court must decide if the common-law claims are based upon state law “requirements” that are “‘different from, or in addition to’ the federal ones, and that relate to safety and effectiveness.” *Riegel*, 552 U.S. at 321–22 (citing [§ 360k\(a\)](#)). *Riegel* involved state law claims for strict products liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of a Class III catheter that had received FDA premarket approval. *Id.* at 320. All of the plaintiffs’ claims

related to the safety and effectiveness of the catheter, so the critical inquiry was whether the state claims constituted “requirements” subject to preemption under the MDA. *Id.* at 323. The Supreme Court answered yes. *Id.* at 323–24. “State tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.” *Id.* at 325.

*5 Even though state common law claims constitute requirements, they will not be preempted unless they are “‘different from, or in addition to,’ the requirements imposed by federal law.” *Id.* at 330 (citing [§ 360k\(a\)\(1\)](#)). “Thus, [§ 360k](#) does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)). Because the claims in *Riegel* alleged the catheter violated state tort law despite compliance with federal requirements, the claims involved state requirements that were different from, or in addition to, federal requirements. *See id.* The *Riegel* plaintiffs belatedly argued that their lawsuit raised parallel claims, but the Supreme Court declined to address that argument. *Id.* Accordingly, the Supreme Court affirmed the dismissal of the plaintiffs’ claims as preempted. *See id.* at 320–21, 330.

At issue here is whether the Plaintiffs have sufficiently alleged parallel claims so as to avoid preemption under [§ 360k](#) and *Riegel*.⁴ The Eleventh Circuit recently addressed this issue in *Wolicki–Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296 (11th Cir.2011). In considering whether the plaintiffs had raised a parallel claim, the court noted that a plaintiff “cannot simply incant the magic words” that a defendant has violated federal regulations. *Id.* at 1301 (internal citation omitted). Rather, the parallel claims must be specifically stated in the initial pleadings and the plaintiff must allege that the defendant violated a particular federal specification concerning the device at issue. *Id.* To properly allege parallel claims, the complaint must further set forth facts pointing to specific [pre-market approval] requirements that have been violated. *Id.* In short, a bare allegation, devoid of factual detail, that the manufacturing processes did not satisfy the FDA’s Pre-Market Approval standards for the device is insufficient to satisfy the requisite elements of a parallel claim, as set forth in *Riegel*. The complaint in *Wolicki–Gables* contained Florida state law claims for strict liability and negligence concerning alleged design and manufacturing defects in a pump system for back pain, as well as a strict liability claim for failure

to warn. *Id.* at 1301. The district court determined that each claim was preempted by the MDA and dismissed the claims on summary judgment. *Id.* at 1299. The Eleventh Circuit agreed because none of the claims alleged a failure to comply with a FDA regulation that could be linked to the alleged injury. *Id.* at 1301–02. Accordingly, the Eleventh Circuit concluded that the complaint did not contain the elements of a parallel claim, and the state common law claims were therefore preempted. *Id.* at 1302.

4 The parties agree that all of Plaintiffs' claims relate to the "safety and effectiveness" of Medtronic's ICD within the meaning of 21 U.S.C. § 360k(a). See *Riegel*, 552 U.S. at 321–22.

Although the preemption issue in *Wolicki–Gables* arose at the summary judgment stage, rather than pursuant to a Rule 12(b)(6) motion, the Eleventh Circuit's discussion about the pleading requirements for a parallel claim remains instructive here. With these principles in mind, the Court turns to the specific causes of action raised in the complaint.

B. Plaintiffs' Claims

1. Count One—Negligence

*6 In Count One, plaintiffs contend that Medtronic negligently manufactured Leonard's ICD because "the failure of the manufacturing processes for the defibrillators and certain of their components to satisfy the Food and Drug Administration's Pre–Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects(.)" (Pls.' Compl. [1] at ¶ 72.) Besides being a general, conclusory allegation, the complaint does not point to specific premarket approval requirements that have been violated or allege any facts as to how those violations occurred. Without these allegations, Count One amounts to nothing more than the speculative proposition that "full compliance would have resulted in a problem-free device." *Clark v. Medtronic, Inc.*, 572 F.Supp.2d 1090, 1094 (D.Minn.2008). Yet, as other courts have recognized, negligence is not the only reason a Medtronic ICD may fail. Other factors such as "medical complications, body rejection phenomena, allergic reaction, and surgical techniques" can all play a role in its proper operation. *Id.*

Nor does the complaint allege any facts causally linking the alleged violations to injuries or harm suffered by plaintiff Leonard. See *Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *10 (D.Colo. May 12, 2010) ("Thus, merely alleging some

violation of FDA regulation will not suffice to establish a 'parallel' claim, unless Plaintiff can factually demonstrate that the violation actually caused her injuries."). Plaintiffs allude to Medtronic's recall of ICDs, but never allege in the complaint that Leonard was harmed because his ICD suffered the battery shorting problem that prompted the recall. Compare *Phillips v. Stryker Corp.*, 2010 WL 2270683, at *2, 7 (E.D.Tenn. June 3, 2010) (finding parallel claim raised where complaint alleged plaintiff required surgery because his device had the same manufacturing defect which had caused the device's recall). This causal connection is "a critical element" of a properly pled parallel claim because premarket approval does not mean that a medical device will never result in injuries, only that the benefits outweighs the risks of probable injuries. *Franklin*, 2010 WL 2543579, at *10; *Riegel*, 552 U.S. at 318 (noting approval of a ventricular assist device for children with failing hearts even though the device had less than a 50 percent success rate in keeping those children alive). Accordingly, Count One's unsubstantiated allegations of FDA violations do not state a proper parallel claim under *Riegel*.⁵ See *Wolicki–Gables*, 634 F.3d at 1301; *Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1301 (D.Colo.2008) (finding that complaint's unsupported allegations that artificial hip implant device did not satisfy the FDA's premarket approval standards "are not sufficient to sustain plaintiff's burden of pleading under *Twombly*"). Accordingly, because Plaintiffs have failed to raise a valid parallel claim, their negligence claim in Count One is preempted under § 360k. See *Wolicki–Gables*, 634 F.3d at 1301–02.

5 Plaintiffs urge the Court to follow *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp.2d 830, 840–41 (S.D.Ind.2009), in which the district court concluded that the plaintiff satisfied *Twombly* merely by alleging that the manufacturing process did not satisfy the FDA's premarket approval standards. The *Hofts* decision has been criticized by several courts for its lax interpretation of *Twombly*'s standards. See, e.g., *Anthony v. Stryker Corp.*, 2010 WL 1387790, at *5 (N.D.Ohio Mar.31, 2010); *Covert v. Stryker Corp.*, 2009 WL 2424559, at *13 (M.D.N.C. Aug.5, 2009). More importantly, the Court must apply Eleventh Circuit law, which requires more than a general allegation of an FDA violation to state a valid parallel claim. See *Wolicki–Gables*, 634 F.3d at 1301.

2. Count Two—Strict Liability: Design and Manufacturing Defect

*7 Plaintiffs repeat the same conclusory allegation of an FDA violation in Count Two, *albeit* this time calling the unspecified violation, a strict liability tort. Specifically, plaintiffs state that Medtronic's "manufacturing process for the defibrillators and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices ... which resulted in unreasonably dangerous manufacturing defects." (Pls.' Compl. [1] at ¶ 80.) Plaintiffs again allege no facts to identify the particular premarket approval requirements that were violated. The complaint also fails to allege how those requirements were violated, or link any violations to Leonard's alleged injuries and death. Like Count One, Count Two does not raise a valid parallel claim, and it is therefore preempted under § 360k. See *Wolicki-Gables*, 634 F.3d at 1301.

3. Count Three—Negligence Per Se

In Count Three, plaintiffs allege that Medtronic's acts, including designing, manufacturing, labeling, and distributing the recalled ICDs, "constitute an adulteration, misbranding, or both" which is prohibited by the Food and Drug Act. See 21 U.S.C. §§ 331(a) and 333(a)(2). (Pls.' Compl. [1] at ¶¶ 87–88.) Plaintiffs further allege that Medtronic's acts constitute a breach of duty subjecting it to civil liability under theories of negligence per se. (*Id.* at ¶ 88.)

In Georgia, a defendant is considered negligent per se based upon violation of a statute if there is evidence that the defendant violated the statute, the injured person was in the class the statute was intended to protect, the injured person suffered the type of harm the statute intended to guard against, and the alleged negligence per se proximately caused the injuries. *Norman v. Jones Lang LaSalle Americas, Inc.*, 277 Ga.App. 621, 628, 627 S.E.2d 382 (2006). In general, the MDA does not preempt a state law prohibiting the manufacture of adulterated or misbranded devices, unless the state law imposes a substantive requirement—for example, a labeling requirement—that differs from, or adds to, a federal requirement under the MDA. See 21 C.F.R. § 808.1(d)(6)(ii) (2008).

Plaintiffs do not, however, allege that Medtronic is negligent per se for violating a state misbranding law. Rather, Count Three alleges that Medtronic violated the FDCA's prohibition against adulteration and misbranding. There is no private

right of action for violations of the FDCA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions."). Instead, all proceedings to enforce or restrain violations of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Consequently, "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA —that is, when the state claim would not exist if the FDCA did not exist." *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 777 (D.Minn.2009).

*8 For example, the Supreme Court held in *Buckman* that a state-law claim that a defendant made fraudulent statements to the FDA, in violation of FDCA disclosure laws, was impliedly preempted by § 337(a) because the claim "would not be relying on traditional state tort law which had predated the federal enactments in question." *Buckman*, 531 U.S. at 352–53. The same is true here—plaintiffs' claim of negligence per se would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law. Plaintiffs cannot create a private right of action under the guise of a state law claim. See *Parker*, 584 F.Supp.2d at 1301 (explaining that plaintiffs "cannot escape preemption by reference to provision of the FDCA that govern the sale of adulterated and misbranded devices because there is no private right of action under the FDCA"); accord *Franklin*, 2010 WL 2543479, at *8 (concluding that § 337(a) impliedly preempted a negligence per se claim that alleged Medtronic violated the FDCA by selling a misbranded and adulterated ICD). Accordingly, Count Three is impliedly preempted by § 337(a).

4. Count Four—Strict Liability: Failure to Warn

Plaintiffs allege in Count Four that Medtronic "failed in providing timely and adequate warnings or instruction regarding its devices with a known design and/or manufacturing defect." (Pls.' Compl. [1] at ¶ 94.) Additionally, Count Four claims that these defects render Leonard's ICD "inherently dangerous for its intended use" and that Medtronic is strictly liable to Leonard's heirs for the pain and suffering he suffered as a result of Medtronic's conduct. (*Id.* at ¶¶ 95–96.) In their response, plaintiffs explain that their failure to warn claim is based on a manufacturer's duty under Georgia's learned intermediary doctrine to warn

the patient's doctor of dangers involved with a product. (Pls.' Resp. to Def.'s Mot. to Dismiss [9] at 15.)

This claim is preempted by the MDA. The Eighth Circuit concluded a similar failure to warn claim, about alleged "known defects" associated with a wire in an ICD, was preempted under § 360k:

In the Master Consolidated Complaint, Plaintiffs alleged that Medtronic failed to adequately warn consumers of "known defects" and that the Sprint Fidelis Leads presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect. These claims are preempted by § 360k. The FDA's [premarket] approval includes specific language for Class III device labels and warnings. Plaintiffs did not allege that Medtronic modified or failed to include FDA-approved warnings. Rather, they alleged that, by reason of state law, Medtronic was required to give additional warnings, precisely the type of state requirement that is "different from or in addition to" the federal requirement and therefore preempted. *See Riegel*, 552 U.S. at 330, 128 S.Ct. 999, 169 L.Ed.2d 892.

In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1205 (8th Cir.2010). As in the latter case, plaintiffs do not allege that Medtronic failed to give the FDA-approved warnings or instructions associated with Leonard's ICD. Nonetheless, plaintiffs contend that Medtronic still violated a state law duty to warn physicians about the ICD's manufacturing and design defects. Plaintiffs' claim would thus impose different requirements under state law than those required under federal law. Consequently, it is preempted under § 360k. *See id.*

*9 Plaintiffs also cannot base a parallel claim on Georgia's learned intermediary doctrine.⁶ Even if Medtronic breached a state law duty to warn a physician, plaintiffs have "not pointed the court to any FDA regulation that requires a device manufacturer to unilaterally contact doctors ... regarding a potential device defect without FDA involvement." *Franklin*, 2010 WL 2543579, at *6. In order to state a parallel claim, the state and federal requirements must be "genuinely equivalent." *Wolicki-Gables*, 634 F.3d at 1300 (quotation marks and citations omitted). "State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Id.* (quotation marks and citation omitted). Given that Plaintiffs have not identified any federal law requiring manufacturers to warn individual doctors about the safety and effectiveness of a device, their claim would hold Medtronic

liable under state law without having violated an equivalent federal law. Moreover, it would impose a duty under state law that is different from that required under federal law. Accordingly, plaintiffs have failed to raise a parallel claim that escapes preemption under § 360k. *See id.; Franklin*, 2010 WL 2543579, at *6.

⁶ Under the learned intermediary doctrine, the manufacturer of a medical device has a duty to give adequate warnings about the device's dangers to the patient's doctor, who serves as a learned intermediary between the manufacturer and the patient. *McCombs v. Synthes (U.S.A.)*, 277 Ga. 252, 253, 587 S.E.2d 594 (2003).

5. Count Five—Breach of Implied Warranty

In Count Five, plaintiffs state that Medtronic "impliedly warranted its products to be of merchantable quality and safe and fit for their intended use." (Pls.' Compl. [1] at ¶ 99.) Contrary to this warranty, plaintiffs allege the ICD is unreasonably dangerous and unfit for its intended purpose. (*Id.* at ¶ 100.)

Riegel affirmed the dismissal of this same claim, as preempted under § 360k. *Riegel*, 552 U.S. at 320–21, 330. As the Court explained, state law that requires a device "to be safer, but hence less effective," than the FDA-approved model would interfere with the federal regulatory scheme. *Id.* at 325. In order to avoid preemption and qualify as a parallel claim, the Supreme Court stated the claim would have to be based on a violation of FDA regulations. *Id.* at 330. Here, Count Five does not allege any FDA violation. The claim is therefore not a parallel claim and is preempted under § 360k. *Id.*

In their response, plaintiffs cite a FDA regulation that lists examples of state requirements that are not preempted under the MDA, including the Uniform Commercial Code's warranty of fitness. *See* 21 C.F.R. § 808.1(d)(1). Whether or not this regulation applies to plaintiffs' claim, plaintiffs failed to plead in their complaint a U.C.C. violation. A pleading must give a defendant "fair notice" of the basis for a claim. *Am. Dental Ass'n*, 605 F.3d at 1288 (quoting *Conley v. Gibson*, 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)). Plaintiffs did not do so here. The Court therefore dismisses Count Five on grounds of preemption.

6. Count Six—Breach of Express Warranty

*10 Plaintiffs state in Count Six that Medtronic's "promotional statements and product literature expressly warranted to plaintiff that the ICD was safe, capable of reducing risk or severity of heart failure, [and] was a highly reliable product in comparison to the conventional product line." (Pls.' Compl. [1] at ¶ 103.) Medtronic allegedly breached this warranty by selling an ICD with known design and manufacturing defects. (*Id.* at ¶ 106.)

Riegel did not address a breach of express warranty claim.⁷ Nor has the Eleventh Circuit decided whether a breach of express warranty claim can be preempted by the MDA. Other federal courts remain divided over the issue. *See Franklin*, 2010 WL 2543579, at *7 (noting "continuing split amongst the courts" post-*Riegel*); *Parker*, 584 F.Supp.2d at 1302–03 (collecting pre-*Riegel* cases on both sides of the issue). Plaintiffs rely on the Seventh Circuit's pre-*Riegel* observation that express warranties "arise from the representations of the parties and are made as the basis of the bargain between them." *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir.1997). The Seventh Circuit suggested that an express warranty claim might escape preemption because a state judgment that a party has breached an express representation might not necessarily interfere with the FDA's premarket approval system. *Id.* These comments were merely dicta, however, because the plaintiffs had not specifically raised an express warranty claim. *Id.*

⁷ Although the district court did not initially dismiss this claim as preempted, the district court subsequently dismissed it on summary judgment, and the plaintiff did not appeal this issue to the Supreme Court. *Riegel*, 552 U.S. at 321 n. 2.

In any event, the express representation claims in this case would interfere with the FDA's premarket approval regime. Plaintiffs claim that Medtronic expressly warranted the ICD to be safe and highly reliable. In order to prove that Medtronic breached this warranty, Plaintiffs would need to show that the ICD was not safe and reliable, a finding that would directly conflict with the FDA's premarket approval of the device as reasonably safe and effective. *See* 21 U.S.C. § 360e(d). Moreover, if these warranties were made in materials approved by the FDA in the premarket approval process, then allowing a claim to proceed under Georgia law would subject Medtronic to state duties above and beyond the federal requirements. *See Wheeler v. DePuy Spine, Inc.*, 706 F.Supp.2d 1264, 1271 (S.D.Fla.2010) (finding preempted a breach of express warranty claim based on statements in

a FDA-approved brochure). This claim thus falls within § 360k's preemption clause prohibiting state requirements that are in addition to, or different from, federal requirements. *See In re Medtronic*, 623 F.3d at 1208 ("The district court correctly concluded that this express warranty claim interferes with the FDA's regulation of Class III medical devices and is therefore conflict preempted.").

In their response, plaintiffs argue that their "warranty claim parallels the FDA regulation" because they do not allege that Medtronic's FDA-approved label was defective. (Pls.' Resp. to Def.'s Mot. to Dismiss [9] at 17.) Plaintiffs declare they are "perfectly happy with the label" but that "Medtronic did not live up to the FDA-approved promises contained in its label and that Lorenzo Leonard died as a result." (*Id.* at 17–18.) Plaintiffs lift this language verbatim from the district court's decision in *Hofts*. *See Hofts*, 597 F.Supp.2d at 839 (relying on *Mitchell*, 126 F.3d at 915, to find that a breach of express warranty claim is a parallel claim and not preempted).

*11 *Hofts*, however, conflicts with the Supreme Court's and the Eleventh Circuit's definition that a parallel claim is a state law claim "premised on a violation of FDA regulations[.]" not on a defendant *complying* with one. *Riegel*, 552 U.S. at 330; *Wolicki-Gables*, 634 F.3d at 1300–01. Here, plaintiffs concede that Medtronic complied with the FDA's labeling requirements. A finding that Medtronic violated state law by not living up to the FDA-approved promises in its label would necessarily conflict with the FDA's determination that the label was not false or misleading. *See Riegel*, 552 U.S. at 318 ("The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c (a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e (d)(1)(A)."). Thus, Plaintiffs' claim is not based on state duties that parallel federal requirements. *See id.* at 330; *Parker*, 584 F.Supp.2d at 1303 ("Plaintiff's express warranty claim would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements."). Count Six is therefore preempted under § 360k.

7. Count Seven—Misrepresentation by Omission

Count Seven alleges that Medtronic "misrepresented the mechanical soundness and reliability of its ICD devices to the general public through promotional and marketing campaigns." (Pls.' Compl. [1] at ¶ 109.) Further, Count Seven states that Medtronic concealed and withheld information about the ICD's "manufacturing defects and high risks

of failure.” (*Id.* at ¶ 111.) Plaintiffs clarify in their response that Count Seven is actually a fraud claim; they contend that Medtronic “knowingly concealed, intentionally misrepresented, and knew or should have known the dangers of their ICD.”⁸ (Pls.’ Resp. to Def.’s Mot. to Dismiss [9] at 19.)

⁸ In reply, Medtronic contends that plaintiffs have not pled their fraud claim with the requisite particularity under **Federal Rule of Civil Procedure 9(b)**. **Rule 9(b)** entails a heightened level of specificity which means a complaint must typically identify “(1) the precise statements, documents, or misrepresentations made; (2) the time and place of and person responsible for the statement; (3) the content and manner in which the statements misled the plaintiffs; and (4) what the defendants gained by the alleged fraud.” *Ambrosia Coal & Const. Co. v. Pages Morales*, 482 F.3d 1309, 1316–17 (11th Cir.2007). As previously discussed, all of plaintiffs’ claims fail to satisfy the pleading requirements of **Rule 8(a)**. The Court also agrees with Medtronic that the fraud claim’s general allegations do not meet any of the particularity requirements of **Rule 9(b)**. *See id.*

This claim is preempted because it would require Medtronic to give different, additional warnings about the ICD’s safety and effectiveness, which is strictly prohibited without FDA approval. “Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in … labeling … that would affect safety or effectiveness.” *Riegel*, 552 U.S. at 319. Plaintiffs do not contend in Count Seven that Medtronic violated any FDA regulations concerning the device’s FDA-approved warnings and instructions. Plaintiffs’ fraud claim thus necessarily imposes state requirements that are “ ‘different from, or in addition to’ ” the federal ones. *Id.* at 330. Consequently, Count Seven does not state a parallel claim and is preempted under § 360k. *See id.* at 330; *In re Medtronic*, 623 F.3d at 1205 (finding preempted a claim that Medtronic failed to adequately warn consumers of known defects about a device notwithstanding compliance with federal requirements).

8. Count Eight—Unjust Enrichment

*12 Plaintiffs allege in Count Eight that “[a]s an intended and expected result of their conscious wrongdoings as set forth in this Complaint, defendant has profited and benefited [sic] from payments Lorenzo Leonard made for the Medtronic

Device.” (Pls.’ Compl. [1] at ¶ 117.) Plaintiffs claim that Leonard expected the ICD to be safe and medically effective, and that Medtronic’s failure to meet this expectation unjustly enriched Medtronic. (*Id.* at ¶¶ 118–19).

As with plaintiffs’ other claims, success on this claim depends on a finding that Leonard’s ICD was not safe and effective, despite FDA premarket approval. Count Eight does not specifically name a FDA violation by Medtronic, referring only generally to the “wrongdoings” set forth in the complaint. (*Id.* at ¶ 117.) As discussed, plaintiffs’ unsubstantiated allegations in Counts One and Two that Medtronic failed to satisfy the FDA’s premarket approval standards do not sufficiently state the elements of a parallel claim. *See Wolicki–Gables*, 634 F.3d at 1301–02. Moreover, “because this claim is entirely contingent upon Defendant’s liability for the above preempted claims, this claim is similarly preempted.” *Franklin*, 2010 WL 2543579, at *10 (finding preempted plaintiff’s claim for negligent infliction of emotional distress because it was derivative of plaintiff’s other preempted claims). Plaintiffs’ claim of unjust enrichment is therefore preempted under § 360k.

IV. Leave to Amend Complaint

In their response, plaintiffs request an opportunity to amend their complaint should the Court find that dismissal is warranted. (Pls.’ Resp. to Def.’s Mot. to Dismiss [9] at 22.) Under **Federal Rule of Civil Procedure 15(a)**, leave to amend shall be freely given “when justice so requires.” **FED. R. CIV. P. 15(a)(2)**. Plaintiffs make several new factual allegations in their response related to Leonard’s injuries and death which are not in the original complaint. These allegations relate to plaintiffs’ ability to state a valid claim for relief and to the timeliness issue. Further, the complaint was filed several months before the Eleventh Circuit’s decision in *Wolicki–Gables*, which set the parameters for a valid parallel claim under *Riegel*. In the interests of justice, the Court will grant plaintiffs leave to amend their complaint.

CONCLUSION

In sum, plaintiffs’ complaint is replete with conclusory allegations that fail to state a valid claim for relief under **Rule 8(a)**. Additionally, none of plaintiffs’ claims, as currently pled, contain the elements of a parallel claim so as to avoid preemption by the MDA. Defendant’s motion to dismiss is therefore meritorious, and the Court would grant this

motion, except for the plaintiff's request to be allowed to amend its complaint. Because the Court will permit the plaintiff to amend its complaint, the Court therefore **DENIES WITHOUT PREJUDICE** defendant Medtronic's Motion to Dismiss [5].

***13** Plaintiffs may amend their complaint **within 28 days** of this Order. The plaintiffs are on notice, however, that *any* defects in an amended complaint will result in dismissal with prejudice of the particular count. Should plaintiffs *not* amend

their complaint within the above time period, the Court will then order the case to be dismissed with prejudice. The Clerk shall submit this action 29 days after the issuance of this Order.

SO ORDERED.

All Citations

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End of Document

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TAB 36

 KeyCite Red Flag - Severe Negative Treatment
On Reconsideration [Levinson v. Johnson & Johnson Consumer Companies, Inc.](#), D.N.J., August 2, 2010

2010 WL 421091

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Erika LEVINSON and Maria Watkins,
individually and on behalf of all
others similarly situated, Plaintiffs,

v.

JOHNSON & JOHNSON CONSUMER
COMPANIES, INC. and Wal-
mart Stores, Inc., Defendants.

Civil Action No. 09-CV-3317 (DMC).

|
Feb. 1, 2010.

West KeySummary

1 **Antitrust and Trade Regulation**  Nature
and form

Products Liability  Economic losses;
damage to product itself

Products Liability  Cosmetics, soaps, and
hair-care products

Products Liability  Nature and form of
remedy

Store customers failed to state a consumer fraud claim against a store under New Jersey law. Although the customers alleged that they suffered only economic harm, their underlying claims arose out of the store's allegedly defective baby shampoo which contained toxins that created a potential for harm to their children. Therefore the customer's claims were subsumed by the New Jersey Product Liability Act (PLA) which precluded recovery for solely economic harm. [Fed.Rules Civ.Proc.Rule 12\(b\)\(1\)](#), [28 U.S.C.A.](#); [N.J.S.A. 2A:58C-1b\(2\)](#).

2 Cases that cite this headnote

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OPINION

[DENNIS M. CAVANAUGH](#), District Judge.

*1 This matter comes before the Court upon motion by Johnson & Johnson Consumer Companies, Inc. and Wal-Mart Stores, Inc. ("Defendants") to dismiss the complaint of Erika Levinson and Maria Watkins, individually and on behalf of all others similarly situated, ("Plaintiffs") for failure to state a claim pursuant to [Fed.R.Civ.P. 12\(b\)\(6\)](#) and for lack of subject matter jurisdiction pursuant to Fed. R. Civ. 12(b)(1). Pursuant to [Fed.R.Civ.P. 78](#), no oral argument was heard. After considering the submissions of all parties, it is the decision of this Court for the reasons herein expressed that Defendants' motion to dismiss is **granted in part** and **denied in part**.

I BACKGROUND

The Amended Class Action Complaint is brought individually and behalf of all class purchasers ("Class Members") against Johnson & Johnson Consumer Companies, Inc. ("J & J") and Wal-Mart Stores, Inc. ("Wal-Mart") (collectively "Defendants"). Plaintiffs allege that J & J's Baby Shampoo and Wal-Mart's Equate Tearless Baby Wash include and consequently, exposed Plaintiffs' children to "toxic and potentially cancer-causing chemicals[.]" including methylene [chloride](#), an ingredient banned [for use in cosmetics] by the Food and Drug Administration ("FDA"), 1,4-dioxane and formaldehyde." (See Plaintiffs' Complaint ("Pl.Compl."), ¶ 3). "Along with increased risk of [cancer](#), skin irritation and other serious health problems, chronic exposure to low levels of chemicals can lead to [asthma](#) and hypersensitivity in children." (Pl.Compl., ¶ 38).

"Independent Lab Tests found methylene [chloride](#) levels [between .35 ppm and] 1.1 ppm, 1,4-dioxane levels [between 20 ppm and] 38 ppm, and formaldehyde levels of [between

150 and 230] ppm" in J & J Baby Shampoo. (Pl.Compl., ¶ 43). The chemicals are allegedly not disclosed on the J & J label. (Pl.Compl., ¶ 44). "Independent Lab Tests of Equate Tearless Baby Wash revealed methylene chloride levels of 0.57 ppm, 1,4-dioxane levels of 39 ppm and formaldehyde levels of 360 ppm." (Pl.Compl., ¶ 11).

"Plaintiffs and the Class Members were damaged by Defendants' omissions and failure to warn that their Children's Personal Care Products were contaminated with toxic and potentially cancer-causing chemicals." (Pl.Compl., ¶ 4). The J & J Baby Shampoo contains descriptive messages, such as "as gentle to the eyes as pure water[,"] "Ultra Mild" and "Hypoallergenic" and "rinses clean ... gentle enough even for newborns." (Pl.Compl., ¶ 13). Wal-Mart's Equate Tearless Baby Wash contains descriptive messages, such as "an extra mild ... *cleanser* that won't sting baby's eyes," "rinses completely," and is a "hypoallergenic formula." (Pl.Compl., ¶ 51). Plaintiffs assert that the offensive chemicals could have been removed by a process called "vacuum stripping." (Pl.Compl., ¶ 14). Lastly, Plaintiffs remark that children are especially vulnerable and susceptible to the chemicals in question. (Pl.Compl., ¶¶ 35–38).

*2 Count I of the complaint asserts a claim for breach of implied warranty pursuant to the *Uniform Commercial Code* ("UCC") § 2–314. (Pl. Compl. at 71). Count II of the complaint asserts a claim for breach of implied warranties of merchantability and fitness for a particular use. (Pl.Compl., ¶ 83). Count III of the complaint asserts a claim for unfair and deceptive trade practices. (Pl.Compl., ¶ 90). Count IV of the complaint asserts a claim for unjust enrichment. (Pl.Compl., ¶ 98).

II. STANDARD OF REVIEW

"There is a fundamental difference of review under Rule 12(b)(1), where the existence of disputed facts will not preclude the court from evaluating the merits of the jurisdictional claim, and Rule 12(b)(6) where the court is required to accept as true all the allegations of the complaint and all inferences arising from them." *Anjelino v. New York*, 200 F.3d 73, 87 (3d Cir.1999). "[T]he threshold to withstand a motion to dismiss under [Rule] 12(b)(1) is thus lower than that required to withstand a Rule 12(b)(6) motion." *Kehr Packages Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir.1991)).

A. Fed.R.Civ.P. 12(b)(6)

"The [d]istrict [c]ourt, in deciding a motion under Fed.R.Civ.P. 12(b)(6), [is] required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [Plaintiff]." *Phillips v. County of Allegheny*, 515 F.3d 224, 228 (3d Cir.2008). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, [] a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). "[A court is] not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986). "Factual allegations must be enough to raise a right to relief above a speculative level, [] on the assumption that all factual allegations in the complaint are true (even if doubtful in fact)." *Bell*, 550 U.S. at 555–56.

B. Fed.R.Civ.P. 12(b)(1)

"On a Rule 12(b)(1) motion, no presumption of truthfulness attaches to the allegations of the plaintiff." *CNA v. United States*, 535 F.3d 132, 139 (3d Cir.2008). A facial attack "concerns 'an alleged pleading deficiency' whereas a factual attack concerns the actual failure of [a plaintiff's] claims to comport [factually] with the jurisdictional prerequisites." *Id.* (citing *U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir.2007)).

III. DISCUSSION

A. Standing

To bring a suit in a federal court, the plaintiff must have standing pursuant to Article III of the United States Constitution. To establish standing under Article III, the plaintiff must show: (1) injury in fact; (2) causation; and (3) redressability. *Horvath v. Keystone Health Plan E., Inc.*, 333 F.3d 450, 455 (3d Cir.2003); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992).

*3 First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural

or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Id. (citing *AT & T Communications of N.J., Inc. v. Verizon N.J., Inc.*, 270 F.3d 162, 170 (3d Cir.2001)). “The injury must affect the plaintiff in a personal and individual way.” *Pitt News v. Fisher*, 215 F.3d 354 (3d Cir.2000); *Alston v. Countrywide Fin. Corp.*, 585 F.3d 753, 763 (3d Cir.2009).

“[O]rdinarily, one may not claim standing to vindicate the constitutional rights of some third party.” *Pitt*, 215 at 362. “We apply this prudential rule against third party standing even when the requirements of Article III have been met, to ‘avoid deciding questions of broad social import ... [and] to limit access to the federal courts to those litigants best suited to assert a particular claim.’ “ *Id.* (citing *Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 99–100, 99 S.Ct. 1601, 60 L.Ed.2d 66 (1979)). “[W]hen the asserted harm is a ‘generalized grievance’ shared in substantially equal measure by all or a large class of citizens, that harm alone normally does not warrant exercise of jurisdiction.” *Berg v. Obama*, 586 F.3d 234, 239 (2009) (citing *Warth v. Seldin*, 422 U.S. 490, 499, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975)). Furthermore, “[t]he standing inquiry does not change in the context of a putative class action....[S]tanding cannot be predicated on an injury which the plaintiff has not suffered, nor can it be acquired through the back door of a class action.” *Koronthaly v. L’Oreal*, 2008 U.S. Dist. LEXIS 59024, *12 (D.N.J. July 25, 2008).

As a threshold matter, Defendants contend that Plaintiffs lack standing to sue in the instant action given that Plaintiffs failed to allege an injury-in-fact or that the product failed to perform the hair-cleansing benefits for which it was sold. Moreover, in reliance upon this Court’s decision in *Koronthaly*, Defendants assert that Plaintiffs’ demand for a refund of the purchase price as a consequence of exposure to Defendants’ products fails to establish an injury-in-fact and therefore, is not sufficient to confer standing where the alleged harm is no more than

speculative. As a result, Defendants claim that the absence of a cognizable injury and thereby standing in this matter requires dismissal pursuant to Fed.R.Civ.P. 12(b)(1).

In response, Plaintiffs contend that economic injury is sufficient to confer standing in this matter, relying upon *Clinton v. City of New York*, 524 U.S. 417, 118 S.Ct. 2091, 141 L.Ed.2d 393 (1998) and *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286 (3d Cir.2005). Plaintiffs contend that where the product contains undisclosed toxins and an ingredient banned by the FDA, the injury arises at the time of purchase. In distinguishing the *Koronthaly v. L’Oreal* case, citing to this Court’s disposition on a motion for reconsideration, Plaintiffs assert that unlike *Koronthaly* where this Court determined that plaintiff “provided no authoritative evidence that the lead levels in defendants’ lipstick products constitute[d] a dangerous amount or [were] in some way prohibited[,]” the present action involves methylene chloride, a substance banned by the FDA for use in cosmetics. 2008 U.S. Dist. LEXIS 86419, *11 (D.N.J. Oct. 24, 2008). Further, Plaintiffs contend that the Environment Protection Agency (“EPA”) classifies the other chemicals at issue as probable carcinogens. Lastly, Plaintiffs assert that their claims should stand because Plaintiffs have at least raised an issue of fact with respect to whether the chemicals contained in Defendants’ products are dangerous in amount.

*4 The *Koronthaly* case involved the purchase of a lipstick containing lead, the content of which was not subject to FDA regulation. *Id.* at *2–3. However, the lead content of the lipstick appeared dangerous when compared to the lead content regulation imposed by the FDA on candy. *Id.* In the absence of an FDA regulation concerning lead content in lipstick, or other legal prohibition, the plaintiff could not “seek a remedy for a harm that she ha[d] not actually or allegedly suffered.” Moreover, this Court accorded great weight to the decision in *Williams v. Purdue Pharma Co.*, 297 F.Supp.2d 171 (D.D.C.2003), concluding that the “plaintiffs’ allegation of an economic injury in a products liability action was insufficient to establish injury-in-fact” because “without alleging that a product failed to perform as advertised, a plaintiff has received the benefit of his bargain and has no basis to recover purchase costs.” *Id.* at *13–14. Therefore, the *Williams* Court “remarked that benefit of the bargain injury could not sustain a claim of injury in fact.” *Id.*

“The term ‘cosmetic’ means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for

2010 WL 421091

cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.” 21 U.S.C. § 321(i). “In its definition of the term ‘cosmetic,’ the Federal Food, Drug, and Cosmetic Act specifically excludes soap. The term ‘soap’ is nowhere defined in the act. In administering the act, the Food and Drug Administration interprets the term ‘soap’ to apply only to articles that meet the following conditions:”

- (1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and
- (2) The product is labeled, sold, and represented only as soap.

21 § C.F.R. 701.20. Plaintiff asserts and Defendants do not appear to dispute that the Baby Shampoo is classified as a cosmetic rather than soap. Therefore, the allegedly defective products will be treated as a cosmetics subject to the FDA regulation banning methylene chloride.

While the Court agrees that the assertion of an economic injury is not an automatic bar to standing, *Koronthaly* demonstrates that an exception has been recognized in the context of claims concerning defective products, absent a specific legal prohibition precluding particular ingredients or usages. Insofar as Plaintiffs claims pertain to allegedly toxic chemicals that have not been banned by the FDA for use in cosmetics, including 1,4-dioxane and formaldehyde, in accordance with *Koronthaly*, this Court concludes that any potential injury is too remote, hypothetical and/or conjectural to establish standing in this matter. However, insofar as Plaintiffs claims pertain to methylene chloride, a chemical explicitly banned for use by the FDA in any cosmetic, this Court declines to dismiss Plaintiffs' claims pursuant to Fed.R.Civ.P. 12(b)(1) for lack of standing.

B. Choice of Law

*5 As a federal district court sitting in diversity, this Court must apply the choice of law rules of New Jersey, the forum state. See *Claxton Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496–97, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941). New Jersey's choice of law rules mandate that the determinative law is that of the state with the greatest interest in governing the particular issue. The first step is to determine whether a conflict exists between the law of interested states, and

then any conflict shall be determined on an issue-by-issue basis. “Under general conflict of laws principles, where the laws of the two jurisdictions would produce the same result on the particular issue presented, there is a “false conflict,” and the Court should avoid the choice-of-law question.” *Williams v. Stone*, 109 F.3d 890, 894 (3d Cir.1997). If there is a conflict, then the Court must identify the governmental policies underlying the law of each state and how those policies are affected by each state's contacts to the litigation. If the state's law is not related to its contacts with the litigation, then the state does not have an interest in having its law applied to the underlying issue. See *Vezey v. Doremus*, 103 N.J. 244, 510 A.2d 1187, 1189 (N.J.1986). That is, if there is an actual conflict between the two states' laws, the court then determines “which state has the most meaningful connections with and interests in the transaction and the parties.” *Spence-Parker v. Del. Riv. & Bay Authority*, 2009 U.S. Dist. LEXIS 75187, *20, 2009 WL 2602094 (D.N.J. Aug. 21, 2009). Where no actual conflict of law exists, no choice of law need be made. See *Zavala v. Wal-Mart Stores, Inc.*, 393 F.Supp.2d 295, 333 (D.N.J.2005). “If there is no actual conflict, the Court must apply the law of New Jersey.” *LNT Merck Co. v. Dyson, Inc.*, 2009 U.S. Dist. LEXIS 62308, *6 (D.N.J. July 21, 2009) (citing *Lebegern v. Forman*, 471 F.3d 424, 428 (3d Cir.2006)). In that instance, a motion to dismiss under Fed.R.Civ.P. 2(b) (6) should be decided under New Jersey law. See *Gallerstein v. Berkshire Life Ins. Co. of America*, 2006 U.S. Dist. LEXIS 64487, *3, 2006 WL 2594862 (D.N.J. Sept. 11, 2006).

The parties' respective moving papers recognize that the outcome is the same regardless of whether New Jersey State Law or Missouri State Law is applied to this diversity action. Therefore, the parties assert that no conflict of laws issue is present in the instant matter.

C. New Jersey State Law Breach of Warranty, Consumer Fraud and Unjust Enrichment Claims

Defendants assert that dismissal is required with respect to all Plaintiffs' claims because the claims are based on alleged harm caused by a product and as a consequence, are subsumed by the New Jersey Product Liability Act (“PLA”). Plaintiffs contend that the PLA does not apply because their claims are essentially classic breach of warranty and consumer fraud causes of action. Plaintiffs argue that “[w]hile the PLA covers and subsumes causes of action involving physical harms caused by a product, the [Consumer Fraud Act (“CFA”)] and other remedies remain available when the plaintiffs only claim economic injuries involving a product.” (Pl. Br. at 18).

Further, Plaintiffs argue that the PLA does not apply because Plaintiffs do not assert themselves as “claimants” or allege “harm” as defined by the PLA.

*6 The New Jersey Supreme Court decision in *Sinclair v. Merck & Co.* is instructive. In *Sinclair v. Merck & Co.*, the Plaintiffs “alleged that as a result of their direct and prolonged consumption of *Vioxx*, they are at enhanced risk of serious undiagnosed and unrecognized *myocardial infarction*, commonly referred to as “silent heart attack,” and other latent and unrecognized injuries.” 195 N.J. 51, 55, 948 A.2d 587 (2008). In that case, the plaintiffs asserted claims for negligence, violation of the Product Liability Act, violation of the Consumer Fraud Act, breach of express and implied warranties and unjust enrichment. *Id.* In dismissing the complaint in its entirety, New Jersey Supreme Court determined the following,

[p]laintiffs seek to avoid the requirements of the PLA by asserting their claims as CFA claims. However, the Legislature expressly provided in the PLA that claims for “harm caused by a product” are governed by the PLA “irrespective of the theory underlying the claim.” N.J.S.A. 2A:58C-1b(3). We explained in *Lead Paint*, *supra*, that “[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action in relating to harms caused by consumer and other products.” 191 N.J. at 436–37, 924 A.2d 484. As a result, we declared that “[i]n light of the clear intention of our Legislature to include all [product liability] claims within the scope of the PLA, we find no ground on which to conclude that the claims being raised by plaintiffs, regarding an ordinary household product used by consumers, were excluded from the scope of” the PLA. We reach the same conclusion here.

The language of the PLA represents a clear legislative intent that, despite the broad reach we give to the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product. The heart of plaintiffs’ case is the potential for harm caused by Merck’s drug. It is obviously a product liability claim. Plaintiffs’ CFA claim does not fall within an exception to the PLA, but rather clearly falls within its scope. Consequently, plaintiffs may not maintain a CFA claim.

Id. ^{1 2}

1 Although this Court permitted the CFA claims to proceed in *Nafar v. Hollywood Tanning Sys., Inc.*, in that case, the Plaintiff’s claims and basis for distinction of the CFA from the PLA was the purchase of services, rather than the purchase of a defective product. 2007 U.S. Dist. LEXIS 26312, *12–14 (D.N.J. Apr. 5, 2007). CFA claims rooted in services are clearly distinguishable from claims grounded in products. The present action does not involve a claim for defective services.

2 Further, Plaintiffs misconstrue *In re Ford Motor Co. E-350 Van Products*, 2008 U.S. Dist. LEXIS 73690, *48 n. 9 (D.N.J. Sept. 3, 2008), where the Court did indeed find the *Sinclair* case “inapposite” “because, by design, the PLA ‘except[s] actions for harm caused by breach of an express warranty[,]’ which plaintiffs expressly allege[d.]” On the basis of an express warranty, the Court concluded that *Sinclair* decision “does not mandate dismissal of unjust enrichment and state consumer fraud claims where a party does not plead a PLA claim.” *Id.* (internal citations omitted). Plaintiffs do not assert a claim for breach of an express warranty in the present action.

Similarly, at the heart of this matter is the potential for harm caused by the defective products, J & J Baby Shampoo and Wal-Mart Equate Tearless Baby Wash, containing allegedly “toxic chemicals linked to increased *cancer* risk, adverse skin reactions, and other serious health problems.” (See Pl. Compl., ¶ 2). Plaintiffs directly assert that they “were damaged by Defendants’ omissions and failure to warn that their Children’s Personal Care Products were contaminated with toxic and potentially cancer-causing chemicals.” (Pl.Compl., ¶ 4). Therefore, consistent with the *Sinclair* decision, this Court concludes that the PLA subsumes all of Plaintiffs’ claims, effectively precluding Plaintiffs’ claims with respect to the CFA, and otherwise, in the absence of “harm” as defined by the PLA. The Court does not agree that articulating a claim in terms of pure economic harm where the core issue is the potential injury arising as a consequence of the products’ allegedly harmful chemicals converts the underlying defective product claim into an independent and unrelated consumer fraud issue. Limiting a claim to economic injury and the remedy sought to economic loss cannot be used to obviate the PLA.

*7 The assertion of a claim pursuant to the PLA is premised upon a requisite level of harm, including:

(a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.

N.J.S.A. 2A:58C-1b(2). Harm, for purposes of the PLA, does not include pure economic loss. Insofar as Plaintiffs concede that their injury is purely economic, Plaintiffs' claims cannot survive. Therefore, with respect to New Jersey law, in accordance with *Sinclair*, Plaintiffs' complaint is dismissed without prejudice in its entirety.

D. Missouri State Law Breach of Warranty, Consumer Fraud and Unjust Enrichment Claims

Despite the parties' respective beliefs that there is no conflict of law issue present in the instant matter, it is not clear to the Court that product liability laws of Missouri subsume related claims in the same manner as the New Jersey PLA. Therefore, upon dismissal of all New Jersey State Law claims and for purposes of inclusion, the Court will proceed by addressing the viability of Plaintiffs' claims under Missouri State Law. If Plaintiffs have asserted viable claims pursuant to Missouri State Law, then a conflict of law exists and the Court will undertake to ascertain which state has the superior interest in the litigation.

i. Consumer Fraud

Defendants contend that Plaintiffs have no viable claims pursuant to Missouri State Law because Plaintiffs fail to allege any non-speculative, ascertainable loss and fail to plead their claims with particularity in accordance with *Fed.R.Civ.P. 9(b)*. Plaintiffs assert that they "suffered ascertainable losses to the extent that they paid for and got something less than what was promised" and to the extent that Defendants engaged in material omissions of fact with respect to the presence of toxic chemicals in the products at issue. (Pl. Br. at 29, 33). Plaintiffs also present the Court with the results of independent lab tests detecting the presence of methylene chloride in the allegedly defective products.

"A party must plead the circumstances of each element of fraud with particularity." *Owen v. GMC*, 533 F.3d 913, 921 (8th Cir.2008); *Fed.R.Civ.P. 9(b)*. "Although the [Missouri Merchandising Practices Act ("MMPA")] does not sound in tort and does not require a showing of a product defect as a matter of course, the plain language of the MMPA demands a causal connection between the ascertainable loss and the unfair or deceptive merchandising practice." *Id.* at 922. However, if "the alleged unfair practice is the failure to disclose a product defect, there must be a showing that the [product] in fact suffered that defect, or evidence from which the defect reasonably could be inferred, in order to demonstrate an ascertainable loss as a result of [defendant]'s failure to disclose the defect." *Id.* at 923. "The MMPA prohibits "deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce" by defining such activity as an unlawful practice." *Plubell v. Merck & Co.*, 289 S.W.3d 707, 711 (Mo.App.S.D.2009) (citing *Mo. Ann. Stat. § 407.020*). "Civil actions may be brought under the MMPA to recover actual damages by ' [a]ny person who purchases or leases merchandise primarily for personal, family or household purposes and thereby suffers an ascertainable loss of money or property, real or personal, as a result of [an unlawful practice].'" *Id.* (citing *Mo. Ann. Stat. § 407.025.1*). "The MMPA also specifically authorizes class actions where an unlawful practice 'has caused similar injury to numerous other persons.' " *Id.* (citing *Mo. Ann. Stat. § 407.025.2*). To the extent that Plaintiffs' claims pursuant to Missouri State Law concern methylene chloride, a chemical banned by the FDA for use in cosmetics and detected in Defendants' products, Plaintiffs claims may proceed under Missouri State Law.

*8 Although foreclosed by application of the PLA in the instant case, the CFA was enacted to "protect the consumer against imposition and loss as a result of fraud and fraudulent practices by persons engaged in the sale of goods and services." *Smith v. Alza*, 400 N.J.Super. 529, 552, 948 A.2d 686 (2008). "The MMPA was enacted to preserve fundamental honesty, fair play, and right dealings in public transactions." *Owen v. GMC*, 533 F.3d 913, 922 (8th Cir.2008) (citing *Scott v. Blue Springs Ford Sales, Inc.*, 215 S.W.3d 145, 160 (Mo.Ct.App.2006)). Beyond the underlying governmental purpose of the MMPA, the representative Plaintiffs in this action reside in Missouri and presumably,

the purchases of the allegedly defective products occurred in Missouri. J & J is a New Jersey corporation engaged in business throughout the United States, including Missouri. Wal-Mart is an Arkansas corporation engaged in business throughout the United States, including Missouri. Therefore, the Missouri State contacts in the instant matter seem to outweigh New Jersey State contacts. Missouri State Law prevails with respect to this issue.

ii. Breach of Implied Warranty

Defendants assert that Plaintiffs' breach of implied warranty claims should be dismissed because Plaintiffs' complaint fails to allege that the products were not merchantable or failed to perform the function for which they were sold, and because the complaint fails to allege any purpose that is separate and apart from the ordinary purpose. (Def. Br. at 28–29). Plaintiffs' complaint asserts a claim for breach of implied warranties because the goods were allegedly not fit for their ordinary purpose or particular use on children and further, because the products fail to conform to the promises and representations made on the labels. Specifically, Plaintiffs allege that the products are not merchantable because they are contaminated with methylene chloride. (Pl. Br. at 36).

“In an action based on breach of warranty, it is of course necessary to show not only the existence of the warranty but the fact that the warranty was broken and that the breach of the warranty was the proximate cause of the loss sustained.” *Worthy v. Specialty Foam Products*, 591 S.W.2d 145, 149 (Mo.App. S.D.1979). “After establishing the existence of this warranty,” there must be a showing; “(1) that the implied warranty of merchantability had been broken, and (2) that the breach of this warranty was the proximate cause of its loss.” *Id.* “Crucial to the issue of whether or not a seller has breached an implied warranty of merchantability, is the determination of whether or not the goods in question are merchantable.” *Id.* “Merchantable goods must be at least as such as[:].”

(a) pass without objection in the trade under the contract description; and

(b) in the case of fungible goods, are of fair average quality within the description; and

(c) are fit for the ordinary purposes for which such goods are used; and

*9 (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and

(e) are adequately contained, packaged, and labeled as the agreement may require; and

(f) conform to the promises or affirmations of fact made on the container or label if any.

Mo. Ann. Stat. § 407.2–314. The Uniform Commercial Code (“UCC”) limits the recovery of damages to those proximately caused by the breach of warranty and imposes an obligation on the buyer to minimize damages in good faith. *Groppel Co. v. United States Gypsum Co.*, 616 S.W.2d 49, 59 n. 11 (1981). Assuming, without concluding, that the descriptive messages on the alleged defective products constitute promises or affirmations, then, in accordance with the foregoing limitations, Plaintiffs' claims for breach of implied warranties pursuant to Missouri State Law are permitted to proceed.

Although foreclosed by application of the PLA in the instant matter, the underlying purpose of the UCC as recognized by the New Jersey Supreme Court, is “to simplify, clarify and modernize the law governing commercial transactions; to permit the continued expansion of commercial practices through custom, usage and agreement of the parties; and to make uniform the law among various jurisdictions.” *N.J. S.A. 12A:1–102(1); Alloway v. General Marine Indus., L.P.*, 149 N.J. 620, 630, 695 A.2d 264 (1997). Codified under chapter 400 of Missouri State Law, Missouri State Law adheres to the same underlying purposes as New Jersey. See *Excel Bank v. Nat'l Bank of Kansas City*, 290 S.W.3d 801, 803–04 (Mo.App. W.D.2009). Similar to the foregoing analysis, Missouri's contacts with the representative Plaintiffs and the transactions that are the source of the representative Plaintiffs' claims favors the application of Missouri law over New Jersey with respect to this issue.

iii. Unjust Enrichment

Defendants assert that unjust enrichment is not a proper remedy available in this case because Plaintiffs fail to assert that the products failed to perform. By contrast, Plaintiffs assert that they purchased the products conferring a monetary benefit upon the Defendants for useless products that they would not otherwise have purchase, but for the representations that the products were safe, gentle and/or mild. “The elements of a claim of unjust enrichment are: (1) a benefit conferred upon the defendant by the plaintiff; (2) appreciation by the defendant of the fact of such benefit; and (3) acceptance and retention by the defendant

of that benefit under circumstances in which retention without payment would be inequitable.” *Mays-Maune & Co. v. Werner Bros., Inc.*, 139 S.W.3d 201, 205 (Mo.App. E.D.2005). Equitable remedies are coercive remedies like declaratory judgments and injunctions, the latter of which includes specific performance and some types of restitution. *State ex rel Leonardi v. Sherry*, 137 S.W.3d 462, 470 (2004). “Damages and, in some instances, restitution constitute the legal remedies.” *Id.* (internal citations omitted). Generally, equitable remedies are only available when there is a showing of irreparable injury and/or the absence of an adequate remedy at law. See *State ex rel General Dynamics Corp. v. Luten*, 566 S.W.2d 452, 461 (1978). “There is nothing more basic in law than the proposition that there is neither irreparable injury nor lack of an adequate remedy at law when the only harm would be the payment of money, which clearly can be recovered if, in fact, the plaintiff succeeds on the merits of its claims [I]f plaintiff were to prevail, it would have a legal remedy that would allow it to recover any funds

that, *arguendo*, were paid wrongfully.” *Shipley v. Cates*, 200 S.W.3d 529, 541 (2006). Plaintiffs explicitly and exclusively allege economic injury. Therefore, there is no indication that a remedy at law would be inadequate. To the extent that Plaintiffs assert a claim for unjust enrichment pursuant to Missouri State Law, Plaintiffs' complaint is dismissed.

IV. CONCLUSION

*10 For the foregoing reasons, Defendants' motion is **granted in part** and **denied in part**. Plaintiff's complaint is **partially dismissed without prejudice** pursuant to Fed.R.Civ.P. 12(b)(1) and Fed.R.Civ.P. 12(b)(6). An appropriate order accompanies this opinion.

All Citations

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TAB 37

758 Fed.Appx. 777

This case was not selected for publication in West's Federal Reporter. See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also U.S. Ct. of App. 11th Cir. Rule 36-2. United States Court of Appeals, Eleventh Circuit.

Robert N. MARKLAND, as the Personal Representative of the Estate of Carolyn S. Markland, Deceased, Plaintiff-Appellant,
v.

INSYS THERAPEUTICS, INC., a Delaware Corporation, Defendant-Appellee.

No. 17-14607

|

Non-Argument Calendar

|

(December 19, 2018)

Synopsis

Background: Deceased patient's husband, as personal representative of patient's estate, brought wrongful death action against prescription drug manufacturer, alleging that drug caused patient to suffer respiratory depression and ultimately death. Manufacturer moved to dismiss for lack of subject matter jurisdiction and for failure to state claim. The United States District Court for the Middle District of Florida, [Marcia Morales Howard](#), J., 270 F.Supp.3d 1318, granted the motion to dismiss. Husband appealed.

[Holding:] The Court of Appeals held that husband's state law claim was impliedly preempted by federal law.

Affirmed.

Procedural Posture(s): On Appeal; Motion to Dismiss for Failure to State a Claim.

West Headnotes (1)

[1] **Products Liability** Warnings or Instructions

Products Liability Drugs in general

States Product safety; food and drug laws Substance of state-law negligent marketing claim brought by deceased patient's husband against prescription drug manufacturer was allegation that manufacturer violated the Federal Food, Drug, and Cosmetic Act (FDCA), and thus, husband's state law claim was impliedly preempted by federal law; husband alleged that patient's death stemmed from manufacturer's off-label promotion of drug, rather than from manufacturer's failure to satisfy any independent state law duty of care. Federal Food, Drug, and Cosmetic Act §§ 301, 310, [21 U.S.C.A. §§ 331\(a\), 337\(a\)](#).

1 Cases that cite this headnote

Attorneys and Law Firms

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Appeal from the United States District Court for the Middle District of Florida, D.C. Docket No. 3:16-cv-00997-MMH-PDB

Before [MARCUS](#), [WILLIAM PRYOR](#), and [ANDERSON](#), Circuit Judges.

Opinion

PER CURIAM:

Plaintiff Robert Markland appeals the district court's dismissal of his wrongful death claim against Insys Therapeutics, Inc. In his complaint, Markland alleged that his wife, Carolyn Markland ("Carolyn"), died shortly after receiving a prescription drug manufactured by Insys, and he brought a single claim of "negligent marketing" under Florida law. On appeal, Markland argues the district court erred in finding the claim preempted by the Federal Food,

Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301–399h. After careful review, we affirm.

The tragic facts of this case are these.¹ Insys Therapeutics is a pharmaceutical company that manufactures, among other things, a prescription painkiller called Subsys. Subsys is a spray form of [Fentanyl](#), a powerful opioid that is a Schedule II controlled substance. [See 21 U.S.C. § 812\(c\)](#), sched. II (b) (6). The intended use of Subsys is to treat [cancer](#) patients with “breakthrough pain,” i.e., sharp, sudden episodes of pain that occur despite constant treatment with other pain medications. While this is the sole FDA-approved use of Subsys, Markland alleges that Insys engaged in a “fraudulent” and “unlawful” marketing scheme to push doctors to prescribe Subsys “off label” for patients with other kinds of pain.

¹ Because the district court decided this case on a motion to dismiss, we take the facts alleged in the complaint as true. [See Furry v. Miccosukee Tribe of Indians](#), 685 F.3d 1224, 1226 n.2 (11th Cir. 2012).

Carolyn Markland received Subsys, in what the complaint alleges is a prime example of an off-label use of the drug. At the time, she was receiving treatment for chronic back pain resulting from a [degenerative disc disease](#). She regularly took a different opioid, Exalgo, and her pain management physician prescribed Subsys for pain on an as-needed basis. One morning after her physician administered a dose of Subsys, Carolyn suffered respiratory distress and died. Subsys is known to cause respiratory problems, and the medical examiner identified the cause of death as [drug toxicity](#). Robert Markland filed this wrongful death suit as the personal representative of his wife’s estate.

We review [de novo](#) the grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim. [Ray v. Spirit Airlines, Inc.](#), 836 F.3d 1340, 1347 (11th Cir. 2016). We accept the allegations in the complaint as *779 true and view them in the light most favorable to the plaintiff. [Id.](#) Regardless of the district court’s reasoning, “we are free to affirm the district court’s decision on any ground that is supported by the record.” [United States v. Elmes](#), 532 F.3d 1138, 1142 (11th Cir. 2008).

As a starting point, we note that the FDCA says that its requirements may only be enforced by the United States government. 21 U.S.C. § 337(a). In [Buckman Co. v. Plaintiff’s Legal Committee](#), 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001), the Supreme Court explained how

this bar on private enforcement of the FDCA interacts with the background of state tort law. There, patients injured by a medical device sued a consulting company for allegedly making false representations to the FDA in order to get approval to market the device. [Id. at 343, 121 S.Ct. 1012](#). The plaintiffs’ theory was that if the defendant had not made those false statements, the devices would not have been approved and they never would have been injured. The Supreme Court held that these “fraud-on-the-FDA” state tort claims were in conflict with federal law and were therefore preempted. [Id. at 348, 121 S.Ct. 1012](#). The conflict “stem[med] from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against” it in pursuit of a “somewhat delicate balance of statutory objectives.” [Id.](#) In other words, Congress made a specific choice to allow only the government to enforce the FDCA’s requirements, and allowing private litigants to sue for misrepresentations made to the FDA would conflict with that policy decision. [Id. at 348-51, 121 S.Ct. 1012](#).

After [Buckman](#), this Court noted a distinction between claims that rely on FDCA violations and claims derived from “traditional state tort law that predated the federal enactments in question.” [Mink v. Smith & Nephew, Inc.](#), 860 F.3d 1319, 1327 (11th Cir. 2017) (quotations and modifications omitted). Traditional state-law tort claims are not preempted “so long as they don’t seek to privately enforce a duty owed to the FDA.” [Id.](#) The Court’s different treatment of two claims in that case is instructive: a claim based on the defendant’s failure to file a required report with the FDA was held to be preempted, but a traditional manufacturing defect products liability claim was not. [Id. at 1330](#). The key distinction was that a manufacturing defect claim involves a duty that both predates the FDCA and is owed to the individual patient, not to the FDA. [Id.](#)

Here, Markland’s claim is styled as a “negligent marketing” claim, which is not a recognized tort under Florida law. Markland alleges that after Subsys was approved to treat pain in [cancer](#) patients, Insys “unlawfully and negligently began an aggressive marketing campaign to get physicians to prescribe Subsys for other uses including relieving chronic back pain.” More specifically, Markland asserts that Insys made payments to physicians and other medical professionals who prescribed the drug, at the same time urging them to write off-label prescriptions. Among other things, he alleges that Insys paid health care professionals through a sham “Speakers Bureau,” which rewarded physicians who prescribed Subsys under the guise of providing compensation for travel and speeches. He

adds that Insys “intentionally violated requirements imposed by the FDA” regarding the proper use of the drug.

The district court “read the substance of Mr. Markland’s complaint as alleging that Insys violated federal law” and held that his claim was preempted. We agree. A critical premise of Markland’s complaint is that Insys’s promotion of off-label uses was improper, a proposition that can only *780 be established by pointing to federal law. Although the FDCA does not expressly regulate off-label prescriptions, the FDA has penalized companies for the promotion of off-label uses under the misbranding provisions of the Act. See, e.g., [United States v. Caronia](#), 703 F.3d 149, 154 (2d Cir. 2012) (“The government has repeatedly prosecuted -- and obtained convictions against -- pharmaceutical companies and their representatives for misbranding based on their off-label promotion.”). At the same time, however, the FDA also generally permits the off-label prescription of drugs by physicians. See 21 U.S.C. § 396; cf. [Buckman](#), 531 U.S. at 350, 121 S.Ct. 1012 (explaining that the off-label use of medical devices “is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine”).

Notably, Markland has not pointed to any traditional state-law duty owed by Insys to Carolyn that was breached by the company’s marketing of Subsys for off-label use. It is only because of the FDCA and FDA enforcement decisions that

the promotion of off-label uses is prohibited. Indeed, the very concept of a drug use being “off-label” is derived from the FDCA and FDA policymaking decisions.

Markland is correct that under Florida tort law, a negligence claim can be premised on a duty created by a federal statute or regulation. See [Godfrey v. Precision Airmotive Corp.](#), 46 So.3d 1020, 1023 (Fla. Dist. Ct. App. 2010). But preemption is an issue of federal law, and a duty derived from a federal statute is insufficient to prevent preemption. One cannot say that a claim based on a federal statutory duty “rel[ies] on traditional state tort law which [predates] the federal enactments in question[].” [Buckman](#), 531 U.S. at 353, 121 S.Ct. 1012. As with the [Buckman](#) plaintiffs, Markland seeks to enforce a duty that “exist[s] solely by virtue of the FDCA.” [Id.](#) That kind of claim is preempted.

Because we affirm on the ground that Markland’s claim is preempted, we need not express any view on the viability of a negligent marketing claim under Florida law or the application of the learned intermediary doctrine to this case.

AFFIRMED.

All Citations

758 Fed.Appx. 777

TAB 38

147 Fed.Appx. 239

This case was not selected for publication in the Federal Reporter.

Not for Publication in West's Federal Reporter See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also Third Circuit LAR, App. I, IOP 5.7. (Find CTA3 App. I, IOP 5.7) United States Court of Appeals, Third Circuit.

MDNET, INC., Appellant,

v.

PHARMACIA CORPORATION, and Greenstone Ltd. t/d/b/a Greenstone Healthcare Solutions.

No. 03-4782.

Submitted Under Third Circuit
LAR 34.1(a) Jan. 11, 2005.

Decided June 13, 2005.

Synopsis

Background: Internet company that developed virtual private networks for doctors and hospitals sued pharmaceutical company and its wholly owned subsidiary, alleging breach of contract, promissory estoppel, and fraudulent misrepresentation. The United States District Court for the Western District of Pennsylvania, [Gary L. Lancaster](#), J., dismissed for failure to state claim upon which relief could be granted. Internet company appealed.

Holdings: The Court of Appeals, Shapiro, Circuit Judge, held that:

[1] pharmaceutical company and subsidiary were not liable, under Pennsylvania law, for breach of alleged oral agreement;

[2] Internet company failed to state claim for promissory estoppel under Pennsylvania law; and

[3] pharmaceutical company and subsidiary were not liable in fraud.

Affirmed.

Procedural Posture(s): On Appeal; Motion to Dismiss.

West Headnotes (4)

[1] **Contracts** Parol Modification

Under Pennsylvania law, parties could waive or modify clause in prior contract requiring any further agreements between them to be in writing. [Restatement \(Second\) of Contracts](#) § 224.

[2 Cases that cite this headnote](#)

[2] **Contracts** Parol Modification

Pharmaceutical company and its subsidiary did not intend to waive or modify provision of their prior contract with Internet company that required all future agreements to be in writing, and their alleged oral assent to subsequent oral agreement did not impliedly waive or modify requirement of written contract, and therefore pharmaceutical company and subsidiary were not liable, under Pennsylvania law, for breach of alleged subsequent oral agreement.

[8 Cases that cite this headnote](#)

[3] **Estoppel** Future Events; Promissory Estoppel

Internet company failed to state claim for promissory estoppel against pharmaceutical company and its subsidiary under Pennsylvania law, given that parties' prior written contract required any future agreements to be in writing and Internet company alleged no facts showing intention by pharmaceutical company or subsidiary to waive or modify that requirement, so as to show that Internet company could reasonably rely on alleged oral promises by pharmaceutical company or subsidiary to fund Internet company's continued development of virtual private network, and that Internet company pleaded that consideration existed for parties' exchange of promises, while promissory estoppel applied to enforce promise

not supported by consideration. [Fed.Rules Civ.Proc.Rule 12\(b\)\(6\)](#), 28 U.S.C.A.

[18 Cases that cite this headnote](#)

[4] Fraud  Relations and Means of Knowledge of Parties

Continued negotiation of proposed contract between Internet company and pharmaceutical company and its subsidiary, in which parties defined many of essential terms of agreement, made it unreasonable for Internet company to rely on tentative oral statements made by pharmaceutical company or its subsidiary during course of negotiations, precluding their liability to Internet company for alleged fraudulent misrepresentation under Pennsylvania law.

[8 Cases that cite this headnote](#)

***240** On Appeal from the United States District Court for the Western District of Pennsylvania. District Court No. 02-CV-1237. District Judge: The Honorable [Gary L. Lancaster](#).

Attorneys and Law Firms

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[Troy S. Brown](#), Morgan, Lewis & Bockius, Philadelphia, PA, for Pharmacia Corporation, and Greenstone Ltd. t/d/b/a Greenstone Healthcare Solutions.

***241** Before [ROTH](#) and [CHERTOFF](#),* Circuit Judges, and [SHAPIRO](#),** District Judge.

* This case was submitted to the panel of judges Roth, Shapiro ** and Chertoff. Judge Chertoff resigned after submission, but before the filing of the opinion. The decision is filed by a quorum of the panel. [28 U.S.C. § 46\(d\)](#).

** Honorable [Norma L. Shapiro](#), Senior District Judge for the United States District Court for the Eastern District of Pennsylvania, sitting by designation.

OPINION

SHAPIRO, District Judge.

**1 MDNet, Inc. (“MDNet”) filed this action against Pharmacia Corporation (“Pharmacia”) and Greenstone Ltd. (“Greenstone”) for breach of contract, promissory estoppel, and fraudulent misrepresentation. MDNet appeals the district court dismissal for failure to state a claim upon which relief can be granted.

I. FACTS AND PROCEDURAL HISTORY

MDNet is an “Internet e-Health Company” that develops virtual private networks (“VPNs”) for doctors and hospitals.¹ Pharmacia makes and distributes pharmaceuticals. Greenstone is a wholly owned subsidiary of Pharmacia, and does data-mining, data modeling, e-business applications and other marketing tasks. This dispute arose when Greenstone and Pharmacia ended contract negotiations with MDNet. MDNet alleges an oral contract had been formed; Pharmacia and Greenstone disagree.

¹ A VPN is a private computer network that uses a public network such as the Internet to connect users together securely.

In May, 1999, Greenstone and MDNet entered into a three-month trial business arrangement, memorialized in a written contract (“the May 1999 Agreement”); MDNet provided marketing data to Greenstone for \$30,000. The firms found the trial arrangement beneficial, and wanted to expand their venture so that MDNet would develop VPNs for doctors and hospitals and create sales opportunities for Greenstone and Pharmacia. The venture included the development of a VPN for a group of Texas urologists (“Prime Medical”) that would enable Pharmacia to market the prescription drug “[Detrool](#)” to the urologists.

In October, 1999, MDNet, Greenstone, Pharmacia, and Prime Medical agreed by written contract (“the October 1999 Agreement”) that MDNet would develop a VPN for Prime Medical, and Greenstone would have access to the urologists and their data. Greenstone orally agreed to provide \$700,000 in funding. The October 1999 Agreement contained the following clauses:

10. Prime Medical, MDNet, and Greenstone/PNU intend to maintain a dialogue to consider further exploration of their business relationship. However, any binding agreement resulting from such dialogue must be entered into in writing.

[...]

14. This agreement shall continue in effect until any party gives at least 30 days' advance notice of its intention to terminate to the others, provided that this agreement may not be terminated prior to December 31, 2002, except by a non-breaching party upon any breach, default or other failure to perform by any other party hereto.

Representatives of MDNet and Prime Medical met with representatives of Pharmacia and Greenstone on August 17, 2000 to negotiate expansion of the venture. MDNet alleges that Pharmacia and Greenstone ***242** entered into an oral agreement with MDNet ("the August 2000 Agreement"). MDNet claims the terms of the August 2000 Agreement were as follows: 1) Pharmacia would provide \$2,000,000 in funding over two years; 2) Pharmacia would make available a marketing and sales support team; and 3) Pharmacia would receive exclusive access to MDNet's VPN business model and the Prime Medical urologists to promote **Detrol** and other drugs. The parties proceeded to exchange proposed written contracts to formalize the agreement, but they could not reach agreement. Before a written contract was signed, Pharmacia and Greenstone abandoned the negotiations and refused to provide \$2,000,000 in additional funding.

****2** MDNet filed this action alleging the August 2000 Agreement was an oral contract breached by Pharmacia and Greenstone. The breach of contract claim also alleged Pharmacia and Greenstone breached the October 1999 Agreement, but the complaint did not specify the obligations that were unperformed. Additionally, MDNet alleged promissory estoppel and fraudulent misrepresentation. It attached to the complaint copies of the May 1999 and October 1999 Agreements, and a proposed written contract of September, 2000 ("the September 2000 Proposed Contract") that MDNet claims memorialized the August 2000 Agreement.

Pharmacia and Greenstone moved to dismiss all claims for failure to state a claim upon which relief can be granted. They argued an oral contract had not been formed, because the October 1999 Agreement contained a clause requiring that

any further agreements must be in writing. The magistrate judge issued a report and recommendation recommending that the district court grant the motion. The district court adopted the report and recommendation, and granted the motion. This appeal followed.

II. JURISDICTION AND STANDARD OF REVIEW

The district court had subject matter jurisdiction pursuant to **28 U.S.C. § 1332(a)**. This court has jurisdiction pursuant to **28 U.S.C. § 1291**. Our review of a district court dismissal of a complaint pursuant to **Rule 12(b)(6)** is plenary, and we apply the same test as the district court. *Doug Grant, Inc. v. Greate Bay Casino Corp.*, 232 F.3d 173, 183 (3d Cir.2000). A motion to dismiss may be granted only if, accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief. *Id.* A court may consider undisputedly authentic exhibits attached to a complaint without converting a motion to dismiss into a motion for summary judgment. *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir.1993); **Fed.R.Civ.P. 10(c)**. While our standard of review requires us to accept as true all factual allegations in the complaint, we need not accept as true unsupported conclusions and unwarranted inferences. *Doug Grant, Inc.*, 232 F.3d at 183–184. The district court determined, and the parties agree, that Pennsylvania law applies to all substantive questions of law.

III. DISCUSSION

The district court concluded the parties could not have formed an oral contract because a clause in the October 1999 Agreement required further agreements to be in writing. The court held the clause operated as a condition precedent to the formation of a contract, and MDNet had not alleged any conduct on the part of defendants showing their intent to waive the requirement. The court also dismissed ***243** the claim for breach of the October 1999 Agreement, since MDNet failed to specify the obligations Pharmacia and Greenstone had failed to perform. Finally, the court dismissed the claims for promissory estoppel and fraud because MDNet could not have reasonably relied on the oral agreement or defendants' alleged misrepresentations.

A. Breach of Contract

****3** A breach of contract claim requires MDNet to show a contract between the parties, the essential terms of the contract, a breach of a duty under the contract, and resultant

damages. See *Electron Energy Corp. v. Short*, 408 Pa.Super. 563, 597 A.2d 175 (1991), *aff'd*, 533 Pa. 66, 618 A.2d 395 (1993). A valid, binding contract exists when the parties have manifested an intent to be bound, the terms are sufficiently definite, and there is consideration. *In re Estate of Hall*, 731 A.2d 617, 621 (1999), *appeal denied*, 561 Pa. 697, 751 A.2d 191 (2000). Parties may bind themselves contractually prior to the execution of a written document through mutual manifestations of assent, even where a later formal document is contemplated. *Luber v. Luber*, 418 Pa.Super. 542, 614 A.2d 771, 773 (1992), *appeal denied*, 535 Pa. 636, 631 A.2d 1008 (1993). MDNet alleges Pharmacia and Greenstone manifested the intent to be bound during the August 2000 negotiations because their authorized representatives stated they were "in" and "Pharmacia was their partner in this venture." The complaint states the terms of the contract were definite, and the consideration was two million dollars and a sales support team in exchange for exclusive access to the MDNet business model and the Prime Medical VPN. The complaint also alleges Pharmacia failed to provide the two million dollars, and MDNet's value was diminished as a result.

[1] The district court erred in finding the parties could not have formed an oral contract because the clause requiring a written agreement created a condition precedent. The court relied on *Franklin Interiors v. Wall of Fame Management Co.*, 510 Pa. 597, 511 A.2d 761, 762 (1986). In *Franklin Interiors*, the court held that a document was not a contract because it contained a clause stating that the document would not become a contract until approved by an officer of Franklin Interiors; no officer had approved it. *Franklin Interiors* does not directly apply to the facts of this action. A condition precedent to a contract is formed not by past contracts, but the instant contract. See *Restatement (Second) of Contracts* § 224 (1981). The usual examples are option contracts, or contracts requiring financing or insurance. See *Shovel Transfer & Storage Inc. v. PLCB*, 559 Pa. 56, 739 A.2d 133, 139 (1999); *Cambria Sav. & Loan v. Estate of Gross*, 294 Pa.Super. 351, 439 A.2d 1236, 1239 (1982). Where a requirement is contained in a former contract, the parties may waive the requirement by a later oral modification of the former contract. Parties may orally agree to modify a written contract, even where the written contract contains language prohibiting oral modifications. *Universal Builders, Inc. v. Moon Motor Lodge, Inc.*, 430 Pa. 550, 244 A.2d 10, 15 (1968); *C.I.T. Corp. v. Jonnet*, 419 Pa. 435, 214 A.2d 620 (1965). Whether the clause at issue is described as a condition precedent is irrelevant, since parties can waive a condition

precedent. "The requirement of a written authorization may also be considered a condition which has been waived." *Universal Builders, Inc.*, 244 A.2d at 15 (citing 5 Williston on Contracts § 689 (3rd ed.1961)).

**4 [2] An oral waiver or modification of a written contract must be proved by clear, precise and convincing evidence, including conduct by the parties that "clearly shows" *244 the intent to waive the requirement that the amendments be made in writing." *Somerset Community Hospital v. Allan Mitchell & Assocs.*, 454 Pa.Super. 188, 685 A.2d 141, 146 (1996). As the Pennsylvania Supreme Court forcefully stated:

An oral contract changing the terms of a written contract must be of such specificity and directness as to leave no doubt of the intention of the parties to change what they had previously solemnized by a formal document. The oral evidence must be of such a persuasive character that it moves like an ink eradicator across the written paper, leaving it blank so that the parties in effect start afresh in their negotiations and mutual commitments.

Gloeckner v. School Dist. of Baldwin Tp., 405 Pa. 197, 175 A.2d 73, 75 (1961).

In light of the exhibits attached to MDNet's complaint, MDNet failed to plead facts from which one could reasonably infer Pharmacia and Greenstone intended to waive the clause requiring a written agreement. MDNet's complaint makes no reference at all to the writing requirement. MDNet's complaint does not allege that Pharmacia and Greenstone intended to waive or modify Paragraph 10 of the October 1999 Agreement. The complaint does not allege that an authorized agent of Pharmacia or Greenstone ever made any statement waiving the requirement of a writing. MDNet appears to argue that Greenstone and Pharmacia, by oral assent to the August 2000 Agreement, impliedly waived or modified the requirement of written modification. This is not clear and convincing evidence as a matter of law. The district court correctly dismissed the claim for breach of contract.

B. Promissory Estoppel

[3] To make a claim for promissory estoppel, MDNet must allege: 1) Pharmacia and Greenstone made a promise they should have reasonably expected to induce action or forbearance on the part of MDNet; 2) MDNet actually took action or refrained from taking action in reliance on the promise; and 3) injustice can be avoided only by enforcing the promise. See *Crouse v. Cyclops Industries*, 560 Pa. 394, 745 A.2d 606, 610 (2000). Promissory estoppel is applied to enforce a promise not supported by consideration, where there is no binding contract. See, e.g., *Bethlehem Steel Corp. v. Litton Indus., Inc.*, 507 Pa. 88, 488 A.2d 581, 593 (1985).

MDNet's complaint alleges Pharmacia expressly and intentionally promised \$2,000,000 in funding to induce MDNet to continue development of the VPN and forgo other business opportunities. MDNet alleges its reliance was reasonable and justifiable. The district court found MDNet could not have reasonably relied on the oral promises made by appellees because their prior agreement required a writing for a further binding agreement. The requirement of a written contract does not necessarily prevent an oral waiver or modification, but MDNet alleges no facts showing an intention to waive or modify the requirement of a writing. Additionally, MDNet pled that there was consideration for the exchange of promises, where promissory estoppel is applied to enforce a promise not supported by consideration. See, e.g., *Bethlehem Steel Corp.*, 488 A.2d at 593. The district court correctly dismissed the claim for promissory estoppel.

C. Fraudulent Misrepresentation

**5 [4] A plaintiff alleging fraud must plead: (1) a representation; (2) material to the transaction; (3) made falsely, with knowledge of its falsity or recklessness as to its falsity; (4) with the intent of misleading another to rely on it; (5) justifiable reliance on the misrepresentation; and, (6) resulting injury proximately caused by the reliance. *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 560 (1999). "There

is a special *245 kind of proximate cause requirement for fraud and misrepresentation, and plaintiff must demonstrate that a specific statement *caused* a specific harm." *Hurt v. Philadelphia Hous. Auth.*, 806 F.Supp. 515, 530 n. 25 (E.D.Pa.1992) (emphasis in original).

A pleading of fraud is subject to heightened specificity requirements. See Fed.R.Civ.P. 9(b). Plaintiff may not simply point to a bad result and allege fraud, but must "inject precision and some measure of substantiation into the allegations." *In re Chambers Dev. Sec. Litig.*, 848 F.Supp. 602, 616 (W.D.Pa.1994). When multiple defendants are involved, the complaint must plead with particularity by specifying the allegations of fraud applying to each defendant. *Cinalli v. Kane*, 191 F.Supp.2d 601, 609 (E.D.Pa.2002). MDNet failed to specify the defendant or agent making the alleged fraudulent statement.

The district court found MDNet could not prove justifiable reliance because no party could justifiably rely on an oral promise foreclosed by the requirement that a subsequent agreement be in writing. MDNet alleges no facts from which one could reasonably infer an intention to waive or modify the writing requirement. The continued negotiation of the September 2000 Proposed Contract, defining many of the essential terms of an agreement, made reliance on tentative oral statements unreasonable. The district court correctly dismissed the claim for fraudulent misrepresentation.

IV. CONCLUSION

For reasons other than those relied on by the district court, we affirm the dismissal of the MDNet complaint.

All Citations

147 Fed.Appx. 239, 2005 WL 1385906

TAB 39

2011 WL 159674

 KeyCite Yellow Flag - Negative Treatment
Distinguished by [Loreto v. Procter & Gamble Co.](#), 6th Cir.(Ohio), February 22, 2013

2011 WL 159674

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Michelle and John MEDLEY, Christina Benson,
Kristin Cox et al., individually and on behalf
of all others similarly situated, Plaintiffs,

v.

JOHNSON & JOHNSON CONSUMER
COMPANIES, INC., Defendants.

Civil No. 10-cv-02291 (DMC)(JAD).

Jan. 18, 2011.

Attorneys and Law Firms

[Scott M. Lempert](#), Sandals & Associates, P.C., Philadelphia, PA, for Plaintiffs.

[Daniel B. Carroll](#), Drinker, Biddle & Reath, LLP, Florham Park, NJ, for Defendants.

OPINION

DENNIS M. CAVANAUGH, District Judge.

*1 This matter comes before the Court upon motion by Johnson & Johnson Consumer Companies, Inc. (“Defendant”) to dismiss the Plaintiff’s Consolidated Amended Class Action Complaint (“CACAC”) pursuant to Fed.R.Civ.P. 12(b)(1) for lack of subject matter jurisdiction. Pursuant to Fed. R. Civ. Pro 78, no oral argument was heard. After considering the submissions of the parties, and based upon the following, Defendants motion is granted.

I. BACKGROUND

The ten plaintiffs joined in this Complaint allege that Defendant J & J violated the FDA’s ban on methylene chloride as an ingredient in cosmetic products, pursuant to 21 C.F.R. § 700.19. Attorney for Plaintiffs previously brought six virtually identical cases before this Court, four of which were dismissed on August 2, 2010 for lack of standing pursuant

to a motion for reconsideration filed by Defendant Johnson & Johnson.¹ The CACAC allegedly raises new factual and legal issues that distinguish this Complaint from the others that were dismissed by this Court, including allegations that Johnson & Johnson has been investigated by the FDA, and that methyl chloride is an ingredient in its baby shampoo.

¹ *Vercellino v. Gerber Products Co. et al.*, Case 2:09-cv-02905 DMC-MF, CLOSED 8/2/10; *Crouch v. Johnson and Johnson Consumer Cos., Inc. et al.*, Case 2:09-cv-02905 DMC-MF, CLOSED 8/2/10; *Levinson v. Johnson & Johnson Consumer Cos., Inc. et al.*, Case 2:09-cv-03317 DMC-MF, CLOSED 8/2/10; *Boyd v. Johnson & Johnson Consumer Cos. Inc.*, Case 2:09-cv-03135 DMC-MF; CLOSED 8/2/10.

II. LEGAL STANDARD

As the Supreme Court has long held, “Constitutional standing requires (1) injury-in-fact, which is an invasion of a legally protected interest that is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; (2) a causal connection between the injury and the conduct complained of; and (3) it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). Moreover, a “legally and judicially cognizable” injury-in-fact must be “distinct and palpable,” not “abstract or conjectural or hypothetical.” *Raines v. Byrd*, 521 U.S. 811, 819, 117 S.Ct. 2312, 138 L.Ed.2d 849 (1997); *Allen v. Wright*, 468 U.S. 737, 751, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984) (internal quotations omitted) (quoting *Warth v. Seldin*, 422 U.S. 490, 498, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975), and *Los Angeles v. Lyons*, 461 U.S. 95, 101–02, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983)). As the Third Circuit has held, “while it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms.” See *Danvers Motor Co., Inc. v. Ford Motor Co.* 432 F.3d 286, 291 (C.A.3 (N.J.), 2005).

“There is a fundamental difference of review under Fed.R.Civ.P. 12(b)(1), where the existence of disputed facts will not preclude the Court from evaluating the merits of the jurisdictional claim, and Fed.R.Civ.P. 12(b)(6) where the Court is required to accept as true all the allegations of the complaint and all inferences arising from them.” *Anjelino v. New York*, 200 F.3d 73, 87 (Dd Cir., 1999). “[T]he threshold to withstand a motion to dismiss under [Rule] 12(b)(1) is thus lower than that required to withstand a Rule 12(b)(6) motion.”

Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir., 1991).

III. DISCUSSION

*2 The Court accepts Plaintiff's contention that economic injury is sufficient to confer Article III standing such that the Court has subject matter jurisdiction over this case. The Court notes the language of *Danvers Motor Co., Inc. v. Ford Motor Co.* 432 F.3d 286, 293 (C.A.3 (N.J.), 2005) in which the Third Circuit held that "monetary harm is a classic form of injury-in-fact," and that "injury-in-fact is not Mount Everest." In spite of that language, however, Plaintiffs cannot clear the threshold requirement for showing economic injury. As the Court understands the CACAC, the economic injury for which Plaintiffs seeks redress is the price Plaintiffs paid for shampoo, which they then apparently used in bathing their children, without adverse health reactions. Whatever injury they claim to have suffered due to their subsequent discovery of methyl chloride in the shampoo could not, therefore, have been economic.² Simply put, Plaintiffs bought and used shampoo, and subsequently wished that they had not done so because they feared for the future safety of their children. Their assertion that because the product was tainted, the injury occurred at the moment of purchase, is unavailing. Plaintiff's reasoning in the CACAC is circular and unpersuasive as to the contention that Plaintiffs suffered an injury-in-fact. The CACAC avers that "had Plaintiffs known the true nature of Defendant's baby shampoo, they neither would have purchased it nor allowed their children to be exposed to it." This is undoubtedly correct, but the conclusion that "consequently, Plaintiffs have been economically damaged" simply does not follow. (See ECF Doc. 27, page ID# 483). Presumably, had Plaintiffs known about the alleged toxicity of the shampoo prior to using the product they would either have returned it unopened, or not purchased it in the first place. Once the product had been consumed, however, there was no economic injury for Plaintiffs to complain of, and the fear of future injury is legally insufficient to confer standing. Plaintiffs received the benefit of their bargain so long as there were no adverse health consequences, and the product worked as intended, meaning that the hair of Plaintiff's children was cleansed, and their eyes and skin were not irritated. There is nothing in the CACAC to suggest otherwise. The

Court finds that the facts as pled in the CACAC are legally insufficient to demonstrate an injury-in-fact of even the most *de minimis* amount, and that no further restyling of the CACAC could overcome this jurisdictional hurdle. It would be both foolish and impossible to parse and measure the amount of shampoo each Plaintiff used prior to the discovery of taint, and the Court will not entertain such a fractionated analysis. Short of seeking redress for the unused portion of a bottle of shampoo that was discarded subsequent to discovery of the alleged contamination, a practical and legal absurdity, there is simply no cognizable economic injury. The Court need not reach the issue on which the previous four cases were dismissed, namely the contention that methyl chloride was not an "ingredient" as that term is understood by the Food and Drug Administration, although the Court notes that Plaintiff's syllogistic reasoning, that methyl chloride was a "component," and therefore an "ingredient" is neither a factual nor a legal improvement over Plaintiff's previous allegations. To the extent that there is no injury-in-fact, either economic or otherwise, the "per se" adulteration of the product is simply irrelevant to these Plaintiffs, since they have no standing to bring the claim before this Court. Plaintiff should consider this issue to have been fully litigated and thus precluded for future consideration by the Court.

²

It should be noted that Plaintiffs have not alleged economic injury on a theory that they paid a premium price for this brand of shampoo based on Johnson & Johnson's misrepresentation of their product as being safe and non-toxic for children, more so than comparable but less expensive alternatives. See *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2d Cir., 2003).

III. CONCLUSION

*3 For the reasons contained herein, Defendant's motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(1) is granted. An appropriate order follows this opinion.

All Citations

Not Reported in F.Supp.2d, 2011 WL 159674

TAB 40

2017 WL 2063008

Only the Westlaw citation is currently available.
United States District Court, W.D.
Texas, San Antonio Division.

Jo Ann MONK, Individually and as Personal
Representative of the Estate of Jesse Monk, Plaintiff,
v.
WYETH PHARMACEUTICALS,
INC., et al., Defendants.

Civil Action No. SA-16-CV-1273-XR
|
Signed 05/11/2017

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ORDER

XAVIER RODRIGUEZ, UNITED STATES DISTRICT
JUDGE

*1 On this date, the Court considered Defendant Teva
Pharmaceuticals' Motion to Dismiss (Docket no. 21),
Defendants Eon Labs and Sandoz Inc.'s Motion to Dismiss
(Docket no. 22), and the corresponding responses and replies.
After careful consideration, the motions to dismiss are
GRANTED IN PART AND DENIED IN PART.

BACKGROUND

I. Plaintiff's Factual Allegations

Jesse Monk had [atrial fibrillation](#). Docket no. 18 at 6. Doctors
prescribed [amiodarone](#) as a treatment. *Id.* He never received a
Medication Guide describing certain risks associated with his
use of [amiodarone](#) and his pharmacy did not have Medication
Guides to provide to him. *Id.* at 7. After taking [amiodarone](#)
as prescribed for approximately eight years, Monk died in

January 2015. *Id.* at 1, 6. His autopsy revealed that the cause
of death was [amiodarone poisoning](#). *Id.* at 8. Monk's spouse,
Jo Ann Monk, is the plaintiff in this lawsuit, and brings claims
individually and as personal representative of Jesse Monk's
estate. *Id.* at 1. Defendants Teva Pharmaceuticals USA, Inc.,
Eon Labs, Inc., and Sandoz, Inc. are distributors of a generic
form of [amiodarone](#). *Id.* at 6. Defendants are required by Food
and Drug Administration ("FDA") regulations and the Food,
Drug, and Cosmetics Act ("FDCA") to provide Medication
Guides to Monk via his pharmacy. *Id.* at 7-8; *see* 21 C.F.R.
§ 280.24(b).

Jesse Monk was prescribed [amiodarone](#) "off label"—that
is, for a use for which it was not fully approved by the
FDA. *Id.* at 6. In particular, [amiodarone](#) was approved
by the FDA through a limited "special needs" process,
meaning that it was only approved "as a drug of last
resort for patients suffering from documented recurrent life-
threatening [ventricular fibrillation](#) and [ventricular tachycardia](#)
when these conditions would not respond to other available
anti-arrhythmic drugs and therapies." *Id.* at 5-6. Despite
being approved only for these purposes, doctors prescribed
[amiodarone](#) to Monk for treatment of [atrial fibrillation](#). *Id.*

When Monk had his prescription filled at a local Walgreen's
pharmacy, he was never given a Medication Guide. *Id.* at
7. According to the complaint, Monk did not know that he
was prescribed [amiodarone](#) off label or of the risks of taking
[amiodarone](#), the Medication Guide would have given him this
information, and he would not have taken [amiodarone](#) had he
been fully informed. *Id.*

Plaintiff's live complaint asserts causes of action for
negligence, negligence per se, and gross negligence:

[Defendants] have a duty to market
amiodarone in such a way as
to avoid unreasonable harm to
patient consumers. [Defendants] were
required to provide a Medication
Guide ... They failed to comply with
that requirement and in doing so
breached parallel Texas State law
duties. [Defendants'] failure to provide
amiodarone Medication Guides as
required breached the Texas state
common law duty to adequately warn

of risks association with prescription medicines.

Id. at 11.

Defendant Teva filed a motion to dismiss on March 14, 2017. Docket no. 21. Defendants Eon and Sandoz filed a similar motion that same day. Docket no. 22.

II. The FDA's Drug Approval Framework¹

¹ This background is taken from prior case law and the allegations in Plaintiff's live complaint; it is meant merely to provide context for the factual and legal contentions in this case and not as a comprehensive primer on FDA requirements and regulations.

*² Brand-name prescription drugs must be approved by the FDA before they go to market. Docket no. 18 at 5. To begin this process, the sponsor of a drug submits a new drug application ("NDA"). *Id.* NDAs include a litany of information relating to a drug's safety, effectiveness, proposed uses, warnings, and potential adverse reactions. *Id.* In 1984, Wyeth, a pharmaceutical company that was initially named as a defendant in this lawsuit but has since been voluntarily dismissed by Plaintiff, sponsored approval of [amiodarone](#) under the brand name [Cordarone](#). *Id.* at 5; *see also* Docket no. 20. In doing so, however, [Cordarone](#) obtained FDA approval under an abbreviated "special needs" process whereby a drug is not subject to the full rigor of an NDA but is approved only for certain, limited "special needs." Docket no. 18 at 5. As such, [Cordarone](#) "was approved only as a drug of last resort for patients suffering from documented recurrent life-threatening [ventricular fibrillation](#) and [ventricular tachycardia](#) when these conditions would not respond to other available anti-arrhythmic drugs and therapies." *Id.* at 5–6.

The above procedure applied only to the initial approval of a Wyeth's *brand-name* formulation of [amiodarone](#), but the remaining defendants in this action are manufacturers of a *generic* form of [amiodarone](#). *Id.* at 5. As such, they are governed by a slightly different regulatory process:

In 1984, through the Hatch-Waxman Amendments, Congress

modified these procedures for generic drug manufacturers, creating an expedited process for approving generic drugs. *See* DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984, [Pub. L. 98-417, 98 Stat. 1585](#) (codified in scattered sections of 21 and 35 U.S.C.). In essence, these amendments allow a generic drug manufacturer to piggy-back on the FDA approval of a brand name drug—greatly accelerating the process for receiving approval—provided that the generic drug has active ingredients and labeling identical to that of the FDA-approved brand name drug. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612–13, n. 2 (2011). After the generic drug receives approval, the generic manufacturer is prohibited from making changes to the drug itself or from unilaterally changing the drug's label. *See Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013).

Eckhardt v. Qualitest Pharm., Inc., 751 F.3d 674, 676 (5th Cir. 2014) (citations modified).

Defendants all received FDA approval to manufacture, market, sell, and distribute their generic formulas of amiodarone. Docket no. 18 at 6. Accordingly, they were required by the FDA and FDCA to provide certain labels, warnings, and information. *Id.* Most notably for purposes of this lawsuit, the FDCA and its regulations require generic drug manufacturers to disseminate Medication Guides:

(b) Each manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients by either:

(1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or

(2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product. ...

(e) Each authorized dispenser of a prescription drug product for which a Medication Guide is required under this part shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent) unless an exemption applies under 208.26.

21 C.F.R. § 208.24(b), (e); see also *McLeod v. Sandoz, Inc.*, 4:16-CV-01640-RBH, 2017 WL 1196801, at *9 (D.S.C. Mar. 31, 2017) (“Specifically, 21 C.F.R. § 208.24 provides that ‘[e]ach manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients.’ ”).

DISCUSSION

*3 Defendants attack Plaintiff's state law claims in three ways. First, they argue that these claims are preempted by federal law under *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001). Second, they argue that Plaintiff has not pled the existence of a duty under Texas law because the learned intermediary doctrine requires pharmaceutical distributors to give warnings only to prescribing physicians rather than directly to patients. Third, they argue that Texas law does not recognize a negligence per se claim based on alleged violations of the FDCA or FDA regulations. More generally, Defendants also argue that Plaintiff's complaint does not meet federal pleading standards because it does not differentiate its allegations as between the three defendants.

For the following reasons, most of these arguments fail. The only one of Defendants' arguments that succeeds is that Plaintiff's negligence per se claims should be dismissed; to this extent, the motions to dismiss are GRANTED. In all other respects, the motions are DENIED.

I. Standard of Review

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’ ” *Ashcroft v. Iqbal*, 556

U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim for relief must contain: (1) “a short and plain statement of the grounds for the court's jurisdiction”; (2) “a short and plain statement of the claim showing that the pleader is entitled to the relief”; and (3) “a demand for the relief sought.” FED. R. CIV. P. 8(a). In considering a motion to dismiss under Rule 12(b)(6), all factual allegations from the complaint should be taken as true, and the facts are to be construed favorably to the plaintiff. *Fernandez-Montez v. Allied Pilots Assoc.*, 987 F.2d 278, 284 (5th Cir. 1993). To survive a 12(b)(6) motion, a complaint must contain “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555.

II. Plaintiff properly alleges that Defendants did not comply with the applicable federal regulations.

Initially, the Court dispenses with an argument asserted by Defendants Sandoz and Eon—that Plaintiff's complaint does not allege that Sandoz and Eon violated any FDA regulations. In particular, Sandoz and Eon argue that Plaintiff does not allege their non-compliance with § 208.24(b) because “[t]he mere allegation that [they] did not provide Medications Guides to the Decedent's pharmacy is not sufficient to allege a violation of this regulation.” Docket no. 22 at 8. With reference to the regulatory language quoted above, they point out that one way a manufacturer complies with the regulations is by “[p]roviding the means to produce Medication Guides,” meaning that their failure to provide Medication Guides itself does not violate the regulations. See 21 C.F.R § 208.24(b)(2).

Sandoz and Eon misread the allegations of the complaint. They focus narrowly on Plaintiff's allegation that “Medication guides were not provided to that pharmacy by ... Eon, Sandoz, or any of their distributors.” Docket no. 18 at 7. Plaintiff, however, goes further by adding the following allegations: “Defendants failed to provide a Medication Guide that would reach Jesse Monk,” *id.* at 3; “Jesse Monk's pharmacy did not have Teva, Eon, or Sandoz Medication Guides to provide Jesse Monk as these defendants each failed to distribute them as required,” *id.* at 7. Though the complaint does not track the regulatory language verbatim, the allegation that the pharmacy did not have the Medication Guides necessarily follows from the premise that the pharmacy lacked the Guides themselves and the means to produce them.

*4 Sandoz and Eon also argue that § 208.24(e) imposes no legal obligation to ensure actual delivery of a Medical

Guide to a patient. Instead, they argue, this regulation applies only to authorized distributors, which the pharmacy is but they are not. Sandoz and Eon ignore that subsection (e) does not absolve manufacturers of the requirements of subsection (b) but instead imposes separate requirements on authorized distributors *in addition to* those imposed on manufacturers. As explained above, the complaint adequately alleges that Sandoz and Eon did not comply with subsection (b); thus, whether they also complied with subsection (e) is irrelevant. Accordingly, Sandoz and Eon’s argument that the complaint does not adequately allege a violation of the applicable federal regulations is without merit.

III. Under state law, Plaintiff adequately alleges negligence claims but does not adequately allege negligence *per se* claims.

a. Plaintiff’s state law claims are not preempted by *Buckman*.

Defendants argue that under the Supreme Court’s decision in *Buckman*, Plaintiff’s Texas law claims that are based on Defendants’ failure to provide an FDA-required Medication Guide are preempted. 531 U.S. 341, 352–53 (2001); *see also* 21 U.S.C. § 337(a) (“[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.”). *Buckman* dealt with “fraud-on-the-FDA” claims involving a medical device manufacturer allegedly using fraudulent tactics to obtain FDA approval for a device and plaintiffs subsequently bringing private causes of action against that manufacturer for its misrepresentations to the FDA.² 531 U.S. at 345–46. Recognizing that private, state law causes of action for fraud-on-the-FDA conflict with federal law because they skewed “a somewhat delicate balance of statutory objectives” covered by the FDA, the Supreme Court found that these claims were preempted. *Id.* at 348. The broader lesson from *Buckman*, which Defendants seek to invoke here, is that state law claims that exist “solely by virtue” of FDCA requirements are preempted. *Buckman*, 531 U.S. 341, 352–53 (2001); *see also* *Perdue v. Wyeth Pharm., Inc.*, 209 F. Supp. 3d 847, 851 (E.D.N.C. 2016) (holding that a state law claim is preempted under *Buckman* if “ ‘the existence of these federal enactments is a critical element in [plaintiff’s] case,’ and [if] a plaintiff’s claims ‘exist solely by virtue of the FDCA ... requirements.’ ” (quoting *Buckman*, 531 U.S. at 352)). Indeed, this preemptive effect of *Buckman* has been

extended beyond the fraud-on-the-FDA context by some courts. *See, e.g., Perdue*, 209 F. Supp. 3d at 851–52.

2 After two failed attempts to obtain FDA approval for its device, the manufacturer split the device into component parts and obtained piecemeal FDA approval for these parts. *Buckman*, 531 U.S. at 345–46.

Crucially, however, the *Buckman* Court distinguished preempted “fraud-on-the-agency” claims from those based on “traditional state tort law principles of the duty of care,” recognizing that “certain state-law causes of actions that parallel federal safety requirements” are not preempted. *Buckman*, 531 U.S. at 352–53; *see also* *Perdue*, 209 F. Supp. 3d at 847 (noting that a state law claim is not preempted under *Buckman* if it rests on “ ‘traditional state tort law principles of the duty of care,’ the establishment of which ‘predated the federal enactments in question.’ ... In this manner, *Buckman* does not extend so far as to restrict ‘certain state-law causes of actions that parallel federal safety requirements.’ ” (quoting *Buckman*, 531 U.S. at 352)). This distinction is logical—the reason for preempting fraud-on-the-agency claims is primarily to protect the “somewhat delicate balance of statutory objectives” that could be skewed by interference from private enforcement, but pre-existing state law tort principles alone do not implicate that same concern.

*5 Recently, the Fifth Circuit addressed a claim similar to this one involving a pharmaceutical company’s failure to provide FDA-required warnings. In *Eckhardt v. Qualitest Pharmaceuticals, Inc.*, the plaintiff attempted to assert a cause of action based on generic drug manufacturers’ failure to provide the plaintiff or his physician with any FDA-approved warnings. 751 F.3d 674, 679 (5th Cir. 2014). Ultimately, the Fifth Circuit affirmed the district court’s dismissal of these claims because the plaintiff did not make adequate factual allegations. *Id.* Before doing so, however, the court indicated that because “failing to provide FDA-approved warnings would be a violation of both state and federal law, this is a parallel claim that is not preempted.” *Id.* (emphasis added).

Other decisions from this Court have followed *Eckhardt*. In *Mitchell v. Wyeth*, a case involving similar allegations based on generic amiodarone manufacturers’ failure to provide Medication Guides, Magistrate Judge Mark Lane recommended that the district court deny the pharmaceutical defendants’ motion to dismiss:

[Defendant] argues that under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001), [plaintiff] does not have a private right of action to the manufacturer's duty to provide the Medication Guide. However, despite rejecting a variety of allegedly parallel state tort claims as preempted by *Mensing* and *Bartlett*, the Fifth Circuit recently held in *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 679 (5th Cir. 2014), that an allegation that generic drug manufacturers "failed to provide [plaintiff] or his physician with any of the FDA-approved warnings ... would be a violation of both state and federal law, [and] this is a parallel claim that is not preempted." *Id.* at 679–80....

To the extent [plaintiff] seeks to allege that Defendants failed to comply with their obligation to supply distributors with the FDA-required Medication Guides, and this failure proximately caused [the decedent] to take amiodarone without knowledge of the FDA-approved warnings, such a claim would survive federal preemption under *Eckhardt's* reasoning.

Case No. 1:16-CV-574-LY-ML, Docket no. 73 at 8–9 (W.D. Tex. Jan. 1, 2017) (some citations omitted). The district court summarily adopted this recommendation after a *de novo* review. *Id.* at Docket no. 75 (W.D. Tex. Feb. 9, 2017). Judge Lane previously made similar recommendations in two more amiodarone cases. See *Rusk v. Wyeth*, Case No. 1:14-CV-549-LY-ML, 2015 WL 3651434 (W.D. Tex. June 11, 2005);³ *Priest v. Sandoz*, Case no. 1:15-CV-822-ML-LY, Docket no. 65 (W.D. Tex. December 29, 2016).⁴ As in *Mitchell*, the district court summarily adopted both of these recommendations after conducting a *de novo* review. *Rusk*, Case no. 1:14-CV-549-LY, Docket no. 46 (W.D. Tex. October 16, 2015); *Priest*, Case no. 1:15-CV-822-LY, Docket no. 67 (W.D. Tex. January 31, 2016).

³ Plaintiffs in this case allege that [defendant] was responsible for providing an FDA-mandated 'Medication Guide.' Plaintiffs further allege that [the decedent] never received the Medication Guide, and that 'the Pharmacies' assert 'no manufacturer' was providing the Guides to pharmacists or patients. To the extent Plaintiffs seek to allege that Sandoz failed to comply with its obligation to supply distributors with the FDA-required Medication Guides, and this failure proximately caused [the decedent] to take amiodarone [sic] without knowledge of the FDA-

approved warnings, such a claim would survive federal preemption under *Eckhardt's* reasoning." *Rusk*, 2015 WL 3651434 at *7 (citations omitted).

⁴

"[D]espite rejecting a variety of allegedly parallel state tort claims as preempted ... the Fifth Circuit recently held in *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 679 (5th Cir. 2014) that an allegation that generic drug manufacturers 'failed to provide [plaintiff] or his physician with any of the FDA-approved warnings ... would be a violation of both state and federal law, [and] this is a parallel claim that is not preempted.' *Id.* at 679–80 ... To the extent Plaintiff seeks to allege that [defendant] failed to comply with its obligation to supply distributors with the FDA-required Medication Guides, and this failure proximately caused [the decedent] to take amiodarone without knowledge of the FDA-approved warnings, such a claim would survive federal preemption under *Eckhardt's* reasoning." *Priest*, Case no. 1:15-CV-822-ML-LY, Docket no. 65 at 11–12 (W.D. Tex. December 29, 2016).

*6 Defendants challenge *Eckhardt* and its progeny for failing to provide reasoning based in Texas law to support the proposition that these Medication Guide claims allege a breach of a parallel duty under Texas law. Defendants ignore, though, that regardless of the explanation in *Eckhardt*, this Court is bound by Fifth Circuit precedent, which expressly recognizes that a claim for failure to provide FDA-approved warnings alleges "a violation of both [Texas] and federal law" and that such a claim "is a parallel claim that is not preempted." 751 F.3d at 679.

Defendants also seek to avoid the *Eckhardt* line of cases by arguing that "neither *Mitchell* nor *Eckhardt* contains any substantive preemption analysis under *Buckman* whatsoever." E.g., Docket no. 30 at 8. In *Mitchell*, Judge Lane's recommendation addressed the argument that *Buckman* preempted the plaintiff's Medication Guide claim. *Mitchell*, Case No. 1:16-CV-574-LY-ML, Docket no. 73 at 8. Defendants may disagree with the analysis or object to its depth, but to say that the recommendation does not contain such an analysis is incorrect. As to *Eckhardt*, whether the court meant that the parallel claims were preempted under *Buckman* or under another source of preemption is irrelevant because the court found that "failing to provide FDA-approved warnings would be a violation of state and federal law ... [and] is a parallel claim." Because "certain state-law causes of actions that parallel federal safety requirements"

are not preempted under the express language of *Buckman*, 531 U.S. at 353, and the Fifth Circuit in *Eckhardt* found that claims for failing to provide FDA approved warnings (like Plaintiff's here) are indeed parallel claims, this Court, at most, takes the simple step of connecting the rule of *Buckman* with the finding of *Eckhardt*.⁵

⁵ The court in *Eckhardt* may well have meant that *Buckman* does not preempt these claims, undermining Defendants' argument entirely. Still, Defendants are correct that the court did not mention *Buckman* by name. At most, it is possible that the court never analyzed whether *Buckman* would also warrant preemption in light of its finding that the state law claims there paralleled federal law.

Other case law does not warrant a contrary result. Defendants cite a variety of cases from the Fifth Circuit dealing with other pharmaceutical claims, but none of these cases dealt with the potential preemptive effect of *Buckman* on state law negligence claims such as the ones here. A large number of these cases involved fraud-on-the-FDA claims, like those in *Buckman* that the Supreme Court found skewed the "somewhat delicate balance of statutory objectives" involved in FDA regulation. See, e.g., *Estes v. Lanx, Inc.*, 660 Fed.Appx. 260, 261 (5th Cir. 2016). Another case cited by Defendants, *Morris v. PLIVA, Inc.*, deals specifically with a pharmaceutical manufacturer's *labeling* of its products, and was not a barrier to the Fifth Circuit's subsequent decision in *Eckhardt* (or any of Judge Lane's recommendations). 713 F.3d 774, 777-78 (5th Cir. 2013). Defendants also cite a variety of cases from district courts outside the Fifth Circuit that have found similar claims to be preempted, but these cases interpret other states' laws and lack the binding guidance of a case like *Eckhardt*. See, e.g., *McDaniel v. Upsher-Smith Pharm., Inc.*, 216CV02604JPMCGC, 2017 WL 657778, at *4 (W.D. Tenn. Jan. 26, 2017) (interpreting Tennessee law and correctly characterizing *Eckhardt* as "only persuasive and not binding authority.").

In sum, the Court finds that Plaintiff's claims are not preempted because under *Buckman*, parallel claims are not preempted, and under *Eckhardt*, claims such as Plaintiff's are parallel claims.

b. The learned intermediary doctrine does not bar Plaintiff's claims at this stage.

*7 Under Texas law, "[t]he elements of a negligence cause of action are the existence of a legal duty, a breach of that duty, and damages proximately caused by the breach." *IHS Cedars Treatment Ctr. of DeSoto, Tex., Inc. v. Mason*, 143 S.W.3d 794, 798 (Tex. 2004). Thus, in order to state a cause of action for negligence, Plaintiff must allege the existence of a legal duty under Texas law. Whether Plaintiff has done so turns on Texas' learned intermediary doctrine.

Texas law has long limited a manufacturer or supplier's duty to warn end users of its products in certain situations where an intermediary separates the supplier from the end user. See *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986) ("[A] manufacturer or supplier may, in certain situations, depend on an intermediary to communicate a warning to the ultimate user of a product."). The Texas Supreme Court in *Alm*—a products liability case involving the manufacture of an aluminum bottle cap—hypothesized about the applicability of this doctrine in the prescription drug context while summarizing the reasoning and holdings from lower Texas courts:

In some situations, courts have recognized that a warning to an intermediary fulfills a supplier's duty to warn ultimate consumers. For example, when a drug manufacturer properly warns a prescribing physician of the dangerous propensities of its product, the manufacturer is excused from warning each patient who receives the drug. The doctor stands as a learned intermediary between the manufacturer and the ultimate consumer. Generally, only the doctor could understand the propensities and dangers involved in the use of a given drug. In this situation, it is reasonable for the manufacturer to rely on the intermediary to pass on its warnings. However, even in these circumstances, when the warning to the intermediary is inadequate or misleading, the manufacturer remains

liable for injuries sustained by the ultimate user.

Id. at 591–92 (citations omitted). The Texas Supreme Court ultimately found that there was some evidence in the record to support the jury’s finding that the warnings given by the manufacturer of the bottle cap to the bottler (i.e., the intermediary) were inadequate. *Id.* at 593

Picking up on this language from *Alm*, the Texas Supreme Court later held that the learned intermediary doctrine applies to a pharmaceutical manufacturer’s duty to warn consumers of dangers associated with prescription drugs. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 156 (Tex. 2012). Previously, the Texas Supreme Court “[had] not considered a case that squarely present[ed] the applicability of the learned intermediary doctrine within the context of prescription drug products-liability cases.” *Id.* at 157. But in *Centocor*, the court extended the rule to such a situation:

[W]e hold that a prescription drug manufacturer fulfills its duty to warn end users of its product’s risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has no further duty to warn the end users directly. *But as we have previously indicated, when the warning to the prescribing physician is inadequate or misleading, the prescription drug manufacturer remains liable for the injuries sustained by the patient.*

Id. at 15 (emphasis added).

Plaintiff correctly highlights the emphasized language from *Centocor*. Unlike Defendants’ characterization of Plaintiff’s argument, this language does not signify an exception to the learned intermediary doctrine, but rather is the rule itself. Where warnings to a learned intermediary are adequate, a drug manufacturer fulfills its duty to warn end users of its products under Texas law, but this result occurs *only if* the drug manufacturer provided adequate warnings. Accordingly, the application of the learned intermediary doctrine does not bar Plaintiff’s claims, as this Court recognized in *Mitchell*.

Case No. 1:16-CV-574-LY-ML, Docket no. 73 at 8–9 (“Texas’s learned intermediary doctrine also does not defeat this cause of action.”). Plaintiff has pled that Defendants failed to provide adequate warnings of the dangers of their products, and under Texas law, this sufficiently states a claim. Whether those warnings were in fact adequate—such that the learned intermediary doctrine would shield Defendants from liability—can be considered at the summary judgment phase after the parties have conducted discovery on the issue.

c. Plaintiff’s negligence per se claims are dismissed.

*8 Defendants argue that Plaintiff’s negligence per se claim should be dismissed because Texas law does not recognize a cause of action for negligence per se based on alleged violations of the FDCA. Docket no. 21 at 14. The Court agrees.

“Negligence per se is a tort theory whereby courts use statutes or regulations to define the standard of reasonably prudent conduct.” *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) (citing *Carter v. William Sommerville & Son, Inc.*, 584 S.W.2d 274, 278 (Tex. 1979)). The Court has relatively little guidance on this question because neither the Fifth Circuit nor the Texas Supreme Court has stated whether a violation of the FDCA and FDA regulations can give rise to a negligence per se claim. *Hackett*, 246 F. Supp. 2d at 594.

To support their arguments, Defendants rely primarily on *Hackett*, where this Court found that Texas law did not recognize such a claim. 246 F. Supp. 2d at 546. The Court was persuaded by the thorough analysis of a Texas trial court, which found that under the applicable factors set forth by the Texas Supreme Court, the FDCA and FDA regulations did not give rise to a cause of action for negligence per se under Texas law. *Id.* (discussing and following *Baker v. Smith & Nephew Richards, Inc.*, Case No. 95-58737, 1999 WL 811334, at *8–11 (Tex. Dist. June 7, 1999)⁶). At least two other federal district courts in Texas have relied on *Hackett* and *Baker* to summarily find that “Texas courts ... refuse to recognize a cause of action for negligence per se based on violations of the [FDCA] and FDA regulations.” *Holland v. Hoffman-La Roche, Inc.*, 3:06-CV-1298-BD, 2007 WL 4042757, at *3 (N.D. Tex. Nov. 15, 2007) (quoting *Hackett*, 246 F. Supp. 2d at 594); *see also Jackson v. Tae Jin Kim*, 2:02-CV-200, 2004 WL 6040969, at *4 (E.D. Tex. Sept. 27, 2004) (citing *Baker*, 1999 WL 811334 at *8). The Court is persuaded by the cases cited by Defendants, and agrees that Texas law likely does not

recognize a cause of action for negligence per se based solely on the violation of the FDCA and FDA regulations.

⁶ *Baker* was affirmed, but the appellate court expressly withheld a ruling on this question. *See McMahon v. Smith & Nephew Richards, Inc.*, Case No. 14-99-00616-CV, 2000 WL 991697, at *3, n. 2 (Tex. App.—Houston [14th Dist.] July 20, 2000, no pet.).

Plaintiff's arguments to the contrary are unavailing. First, Plaintiff argues that the cases cited by Defendants were summary judgment decisions that came long after the pleadings stage. *Hackett*'s dismissal of the negligence per se claims, however, came on a Rule 12(c) motion for judgment on the pleadings. *246 F. Supp. 2d at 593–94*. Further, all of these cases, despite being postured as summary judgment decisions, conducted a legal (not factual) analysis of negligence per se claims. Plaintiff next relies on an out-of-circuit decision interpreting Oklahoma law as recognizing a negligence per se claim in these circumstances, but this case is far from binding in any respect and is countered by other out-of-circuit decisions that reach the opposite result. *Compare* Docket no. 28 at 13 (citing *Howard v. Zimmer*, 718 F.3d 1209, 1210 (10th Cir. 2013) for the proposition that Oklahoma law recognizes FDA-based negligence per se claims) *with* *Talley v. Danek Medical, Inc.*, 179 F.3d 154, 157–61 (4th Cir. 1999) (finding that Virginia law did not permit plaintiff to enforce certain violations of FDA regulations through a negligence per se claim). Finally, Plaintiff argues that Judge Lane permitted similar negligence per se claims to proceed in his recommendations in *Rusk* and *Priest*, but as Defendants note, Judge Lane never analyzed these claims; the refusal to dismiss these claims *sua sponte*, especially in the absence of argument from the parties, is not an affirmation of the validity of these claims. Accordingly, Plaintiff's negligence per se claims are dismissed.

IV. Plaintiff's complaint is not deficient for failing to differentiate its allegations among the three defendants.

*9 Finally, the Court dispenses with Defendants Sandoz and Eon's argument that Plaintiff's complaint is inadequate for failing to differentiate its allegations as to each of the three defendants. Docket no. 22 at 13. Though Plaintiff's complaint does not separate its allegations, it specifically identifies each defendant and specifically describes all Defendants' allegedly wrongful conduct. *See, e.g.*, Docket no. 18 at 6 ¶ 31; 7 ¶ 39; 7–8 ¶ 40; 11 ¶ 57–61. The fact that Plaintiff accuses all three defendants of the same wrongdoings is not a basis for dismissal.

CONCLUSION

For the foregoing reasons, Defendant Teva's motion to dismiss (Docket no. 21) and Defendants Sandoz and Eon's motion to dismiss (Docket no. 22) are GRANTED IN PART AND DENIED IN PART. In their Rule 26 Report, the parties indicated that they would provide a status report by May 22, 2017. Docket no. 27. In preparation for a status conference (which will be set at a later time) the parties are ORDERED to provide this status update by June 5, 2017. In addition, the parties are further ORDERED to provide scheduling recommendations in accordance with the Court's form (available at Docket no. 15) by June 5, 2017.

It is so ORDERED.

All Citations

Not Reported in Fed. Supp., 2017 WL 2063008

TAB 41

2004 WL 57084

United States District Court, D. New Hampshire.

Linda E. MOORE and Wallace Moore, Plaintiffs
v.

MEDEVA PHARMACEUTICALS, INC., a/
k/a Celltech Pharmaceuticals, Inc., and
Celltech Pharmaceuticals Ltd., Defendants

No. Civ. 01-311-M.

Jan. 13, 2004.

Attorneys and Law Firms

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ORDER

MCAULIFFE, J.

*1 Linda Moore says that in October of 1998, after receiving a flu vaccine allegedly manufactured, distributed, and/or sold by defendants (and their predecessors), she contracted a "paralytic ailment known as Guillain-Barre Syndrome and other consequential and incidental ailments." Amended complaint (document no. 28), para. 8. Defendant Celltech Pharmaceuticals, Inc. ("CPI") moves for summary judgment, claiming it did not manufacture, distribute, or sell the vaccine in question. Nor, says CPI, did it develop or supply the package information or other warnings included with the vaccine. Plaintiffs object, asserting that there are genuinely disputed material facts with regard to CPI's involvement in the vaccine's chain of distribution.

Standard of Review

When ruling on a party's motion for summary judgment, the court must "view the entire record in the light most hospitable to the party opposing summary judgment, indulging all

reasonable inferences in that party's favor." *Griggs-Ryan v. Smith*, 904 F.2d 112, 115 (1st Cir.1990). Summary judgment is appropriate when the record reveals "no genuine issue as to any material fact and ... the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). In this context, "a fact is 'material' if it potentially affects the outcome of the suit and a dispute over it is 'genuine' if the parties' positions on the issue are supported by conflicting evidence." *Intern'l Ass'n of Machinists and Aerospace Workers v. Winship Green Nursing Center*, 103 F.3d 196, 199-200 (1st Cir.1996) (citations omitted).

Discussion

I. Background.

Complicating the resolution of CPI's pending motion for summary judgment is the fact that the relationships between the entities responsible for manufacturing, distributing, and selling the vaccine is, to say the least, complex. In a prior memorandum, CPI described some of the relevant relationships as follows:

The influenza flu vaccine (the "Vaccine") referenced [in plaintiffs'] interrogatories for the year 1998 was manufactured in the United Kingdom by Medeva Pharma Limited, a corporation organized under the laws of the United Kingdom. Medeva Pharma Limited was formerly known as Evans Medical Limited. The name change to Medeva Pharma Limited occurred on July 6, 1998. Medeva Pharma Limited merged into Celltech Pharmaceuticals, Ltd. on April 2, 2001. Medeva Pharma Limited has since sold the assets related to the manufacture of the Vaccine to Evans Vaccines Ltd. in October, 2000. Evans Vaccines Ltd. is an unrelated company to Medeva Pharma Limited and [CPI].

CPI's Answers to Plaintiffs' Interrogatories, Exhibit 2 to CPI's memorandum in support of its motion in limine (document no. 36). See also CPI's memorandum at 9 n. 3 ("Medeva Pharma Limited [formerly known as Evans Medical Limited]

merged into Celltech Pharmaceuticals, Ltd. on April 2, 2001. On September 9, 2002, this Court granted Plaintiffs' Motion to Amend their Complaint to add Celltech Pharmaceuticals, Ltd. as a defendant in this case. As such, Evans is now essentially a defendant in this case.”).

*2 Based upon CPI's statement of the relationships between the various parties, it would appear that defendant Celltech Pharmaceuticals, Ltd. (“Celltech”) is the successor-in-interest to the entity that manufactured the vaccine in question. In fact, in its answer to plaintiffs' amended complaint, Celltech admitted that “prior to October 2, 1998, it manufactured Fluvirin Lot No. E20228KA”—the vaccine at issue in this case. Celltech's Answer (document no. 55) at para. 6. And, in response to plaintiffs' requests for admissions, Celltech admitted that:

it manufactured the *influenza* vaccine, Fluvirin, used during the 1998–1999 vaccine season and was responsible for its sale, including the development and provision of package labeling and other warnings approved by the Food and Drug Administration and/or other governmental entities. During the 1998–99 *influenza* vaccine season, Celltech Pharmaceuticals, Ltd. shipped packages of Fluvirin, including its approved package labeling directly to, and only to, General Injectables and Vaccines, Inc. (“GIV”), a Virginia corporation. The vaccine was then distributed by GIV. Defendant, Celltech Pharmaceuticals, Ltd. has no knowledge of GIV's distribution methods.

Exhibit 3 to CPI's memorandum (document no. 68), Celltech's Response to Plaintiffs' Request for Admissions at 1–2.

Notwithstanding Celltech's admitted (and, at least according to it and CPI, its exclusive) role in manufacturing the vaccine at issue in this case, preparing and shipping the package inserts approved by the FDA, and contracting for the vaccine's distribution in the United States through General Injectables and Vaccines, Inc., plaintiffs assert that CPI might still be liable to them, based upon the following three factors.

First, plaintiffs point out that CPI's “Medical Information department ... fielded questions from the medical community and its patients regarding medical questions concerning the flu vaccine generally, and Fluvirin, specifically.” Exhibit 1 to plaintiffs' memorandum, CPI's Amended Answer to Plaintiffs' Interrogatory No. 10 at 2. Second, CPI was listed in the Physicians' Desk Reference as an American affiliate of the vaccine's foreign manufacturer. Exhibit 2 to plaintiffs' memorandum, 1999 Physicians' Desk Reference at 3456. And, finally, CPI was registered with the Food and Drug Administration as the United States agent for the vaccine's foreign manufacturer. *See* Plaintiffs' memorandum at 5. *See also* 21 C.F.R. § 207.40(c) (each foreign drug manufacturer required to register with the FDA must provide the name and address of its United States agent).¹

¹ Section 207.40(c) of Title 21 of the Code of Federal Regulations provides, in pertinent, part:

Each foreign drug establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart C of this part. Each foreign drug establishment shall designate only one United States agent.

- (1) The United States agent shall reside or maintain a place of business in the United States.
- (2) Upon request from the FDA, the United States agent shall assist FDA in communications with the foreign drug establishment, respond to questions concerning the foreign drug establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign drug establishment. If the agency is unable to contact the foreign drug establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign drug establishment.

II. Plaintiffs' Claims Against CPI.

Plaintiffs' complaint advances three substantive claims against CPI, as well as three derivative claims by Mr. Moore for loss of consortium. Unfortunately, in opposing CPI's motion for summary judgment, plaintiffs do not describe how the three factors listed above, even if proved at trial, might

possibly give rise to liability on the part of CPI—an entity that did not manufacture, distribute, promote, sell, administer, or provide the package warnings or inserts with regard to the vaccine at issue in this case.²

² While it appears that CPI *did* distribute an influenza vaccine during the 1996–1997 flu season, that was the only year during which it did so; CPI did *not* distribute a vaccine during the 1998–1999 flu season and, perhaps more importantly, it did not distribute the particular vaccine at issue in this case: Fluvirin, Lot No. E20228KA.

*3 In count one of their amended complaint, plaintiffs allege that CPI was negligent insofar as it failed to warn Mrs. Moore of the risks associated with taking the vaccine and that it was “otherwise negligent in manufacturing, selling, and administering the Vaccine to Plaintiff Linda Moore.” Amended complaint at para. 14. First, since plaintiffs have failed to point to any evidence that might suggest CPI had a role in “manufacturing, selling, [or] administering” the vaccine, their negligence claim, to the extent it is based upon such conduct, necessarily fails.

Beyond that shortcoming in their amended complaint, plaintiffs have failed to articulate precisely how (or why) CPI had a duty, independent of those borne by the manufacturer and distributor, to warn Mrs. Moore of the potential risks associated with the vaccine. CPI's role as United States agent for the vaccine's manufacturer obligated it only to act as an intermediary between the manufacturer and the FDA; the regulations upon which plaintiffs rely do not purport to impose any further obligations on a United States agent of a foreign drug manufacturer. And, plaintiffs have failed to point to any case law (binding or persuasive) supporting their assertion that, as a result of its status as the United States agent for the manufacturer (or because it fielded questions about the vaccine, or because of its status as an “affiliate” of the vaccine's manufacturer), CPI assumed the obligation to warn potential recipients of the vaccine of the risks associated with its use. Consequently, in light of the undisputed facts of record, CPI is entitled to judgment as a matter of law with regard to count one (negligence) of plaintiffs' amended complaint.

In count three of their amended complaint, plaintiffs allege that the vaccine was defective and unreasonably dangerous. Amended complaint, para. 22. Accordingly, they say CPI is strictly liable to them for damages. As noted above,

however, the undisputed material facts demonstrate that CPI did not manufacture, sell, distribute, or administer the vaccine in question. And, plaintiffs have failed to articulate how CPI's status as the manufacturer's United States agent, or its listing in the Physicians' Desk Reference as an “affiliate” of the manufacturer, might give rise to strict liability for an (allegedly) unreasonably dangerous product. Nor have plaintiffs cited any judicial opinions that are supportive of their strict liability claim against CPI. CPI is, therefore, entitled to summary judgment as to count three of plaintiffs' complaint.

Count five of plaintiffs' amended complaint alleges that CPI “warranted to Plaintiff Linda Moore that the Vaccine would be free from defects and free from unreasonably dangerous or unsafe qualities,” but that CPI breached that warranty. Amended complaint at para. 28–29. Again, however, plaintiffs' objection to CPI's motion for summary judgment provides little insight into the precise nature of their claims. Plaintiffs do not, for example, identify whether the “warranties” referenced in count five were express or implied. Nor do they identify any case law supportive of their theory of the case.

*4 In their pre-trial memorandum, plaintiffs do say that their claims are governed by “New Hampshire products liability law and the New Hampshire Uniform Commercial Code.” Plaintiffs' Pretrial Memorandum (document no. 29) at 6. Importantly, however, New Hampshire's Uniform Commercial Code imposes warranties (both express and implied) only upon manufacturers, sellers, and suppliers of goods. *See N.H.Rev.Stat. Ann. (“RSA”)* 382-A:2–318. *See also RSA 382-A:2–313, 2–314, and 2–315.* Since plaintiffs have failed to point to any evidence suggesting that CPI manufactured, sold, or supplied the vaccine in question, and because plaintiffs have not identified any other legal theory under which CPI might be liable to them for breach of warranty, CPI is entitled to judgment as a matter of law as to plaintiffs' breach of warranty claim.

Finally, since CPI is entitled to summary judgment on all of Mrs. Moore's claims against it, it is also entitled to summary judgment on all of the derivative claims for loss of consortium advanced by Mr. Moore (counts two, four, and six).

Conclusion

For the foregoing reasons, plaintiffs have failed to demonstrate that there are any genuinely disputed material facts. Given the undisputed material facts, Defendant CPI is entitled to judgment as a matter of law. Accordingly, Celltech Pharmaceuticals, Inc.'s motion for summary judgment (document no. 68) is hereby granted.

SO ORDERED.

All Citations

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TAB 42

2015 WL 9048979

Only the Westlaw citation is currently available.
United States District Court, D. New Jersey.

Steven SHEERAN and Kelly Sheeran, Plaintiffs,
v.
BLYTH SHIPHOLDING S.A., et al. Defendants.

Civil No. 14-5482 (JBS/AMD)

Signed 12/16/2015

Attorneys and Law Firms

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Patrick M. Northen, Esq., Francis P. Maneri, Esq., Jordan M. Rand, Esq., Dilworth Paxson, LLP, 457 Haddonfield Road, Suite 700, Cherry Hill, NJ 08002, for Defendant Holt Logistics Corp.

OPINION

SIMANDLE, Chief Judge:

I. INTRODUCTION

*1 Plaintiff Steven Sheeran filed this action under the Longshore and Harbor Workers' Compensation Act, 33 U.S.C. § 905(b), after he was injured while working aboard the M/V Swan Chacabucco in the Port of Gloucester, New Jersey. His Complaint names a number of different defendants and alleges that all defendants were negligent by collectively breaching two dozen different duties.

Presently before the Court is a motion to dismiss under Fed. R. Civ. P. 12(b)(6) and a motion for sanctions under Fed. R. Civ. P. 11(c) by Holt Logistics Corp. [Docket Items 36 & 53.] Defendant argues that the Complaint must be dismissed because it fails to place Defendant on notice of the particular claims against it, and that sanctions are warranted because the claims against Holt Logistics are entirely groundless. For the reasons set forth below, the Court will grant Defendant's motion to dismiss but will deny Defendant's motion for sanctions.

II. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs' Complaint (Second Amended Complaint ("SAC") [Docket Item 15]) is short and straightforward.¹ On January 13, 2012, Steven Sheeran was working in the hold of the vessel M/V Swan Chacabucco ("the Swan Chacabucco" or "the Ship"), which was berthed in the Port of Gloucester, when his leg was crushed underneath a crane-controlled tray, causing permanent and severe injuries. (SAC ¶¶ 18-19; 22.) He subsequently brought this action,² which named eight business entities as defendants in the Second Amended Complaint, including Holt Logistics Corp. ("Holt Logistics").³

- 1 The facts are taken from Plaintiffs' Second Amended Complaint ("SAC"). For purposes of this motion, the Court must accept Plaintiffs' allegations as true.
- 2 Plaintiffs filed a separate identical complaint under Sheeran v. Blyth Shipholding S.A., Civ. No. 15-272 (Jan. 14, 2015), but both cases have since been consolidated under this action. (Stip. [Docket Item 30] ¶ 1.)
- 3 The Complaint named the following entities: NYK Container Line, Ltd; NYK Line (North America), Inc.; NYK Cool, a/k/a/ Cool Carriers AB; Cool Carriers Chile SA; Cool Carriers USA Inc.; Chartworld Shipping Corp.; Inshape Shipping Services; and Holt Logistics Corp. (SAC ¶¶ 1-8), along with unnamed entities ABC Companies 1-10 and Def. Companies 1-20. Blyth Shipholding S.A. was later substituted as a named defendant for Chartworld Shipping Corp. (Mar. 11, 2015 Stip. [Docket Item 30] ¶ 2.)

Before Holt Logistics Corp. filed the instant motions, the parties had agreed to dismiss three of the entities from the case. (See Mar. 11, 2015 Stip. [Docket Item 30] ¶ 4). A fourth has since been dismissed (see June 29, 2015 Stip. [Docket Item 46]), leaving only Blyth Shipholding S.A. ("Blyth Shipholding"), Inshape Shipping Services ("Inshape Shipping"), NYK Cool a/k/a Cool Carriers AB ("NYK Cool"), and Holt Logistics as the named defendants.

The Complaint does not allege the specific roles and duties of each Defendant in the action. Rather, it pleads generally that all Defendants "owned, leased, operated, managed, possessed and/or controlled" the Swan Chacabucco. (SAC ¶ 9.) It

also alleges that “all Defendants owned, leased, operated, occupied, maintained, managed and/or otherwise controlled the Ship and/or the Port and specifically maintained, managed, oversaw, directed, controlled, contracted for and/or participated in the operation of stevedoring and/or longshoring services on the Ship and/or at the Port.” (*Id.* ¶ 11.)

*2 Holt Logistics is identified as a “business entity with a registered place of business” in Gloucester City, New Jersey. The Complaint alleges that Holt Logistics and Inchape Shipping “were responsible for training, screening, certifying, hiring and/or providing crane operators and/or other persons involved in stevedoring and/or longshoring operations at the Port.” (SAC ¶ 10.)

The Complaint contains three causes of action. Count One alleges negligence. Without identifying each individual defendant’s negligent conduct, Count One enumerates 24 duties allegedly violated by all Defendants, including but not limited to: violating OSHA regulations; failing to properly train employees; failing to warn of dangerous and unsafe conditions; failing to “comply with federal and state statutes, local ordinances, and all other rules, enactments, or regulations applicable”; failing to properly supervise; failing to provide adequate safety protection; failing to evaluate the work performed for potential hazards; and negligently controlling the work performed on premises. (*Id.* ¶ 20.)

Count Two is a personal injury claim brought against all Defendants “in their capacity as ‘owner’ or ‘owner pro hac vice’ of the aforementioned Ship” under the Longshore and Harbor Workers’ Compensation Act (“LHWCA”), 33 U.S.C. § 905(b). (*Id.* ¶¶ 18-24.) Section 905(b) provides an injured longshoreman with a cause of action against a ship owner for negligence, and Plaintiffs allege that Defendants “owned, operated, managed, possessed and/or controlled the Ship which it operated in the navigable waters of the United States.” (*Id.* ¶ 24.) Finally, Count Three is an action by Sheeran’s spouse, Kelly Sheeran, for loss of consortium. (*Id.* ¶¶ 29-31.)⁴

⁴ Because Plaintiffs allege that the Swan Chacabucco was berthed in the Port of Gloucester, New Jersey when the injuries occurred (SAC ¶ 22), the Court exercises subject matter jurisdiction over Plaintiffs’ claims under the maritime jurisdiction statute, 28 U.S.C. § 1333. The Court also has diversity jurisdiction under 28 U.S.C. § 1332, because Plaintiffs are citizens of Pennsylvania

and all Defendants have principal places of business outside of Pennsylvania, and the matter in controversy exceeds \$75,000. (SAC ¶¶ 1-9; 15.)

III. DEFENDANT’S MOTION TO DISMISS WILL BE GRANTED

Holt Logistics filed this motion to dismiss, arguing that in lumping all of the defendants together and accusing them all of the same general negligent conduct, the Complaint fails to put Holt Logistics on notice of the claims against them, as required by Fed. R. Civ. P. Rule 8(a). (Mot. to Dismiss [Docket Item 36-1] at 8-10.) Defendant also contends that Count Two must be dismissed because the Complaint does not contain any factual basis for its allegations that Holt Logistics is the “ship owner” or “owner pro hac vice” of the Swan Chacabucco for purposes of an LHWCA claim. (*Id.* at 10-11.)

The Court agrees with Defendant that Plaintiffs’ Complaint fails to plead the liability of Holt Logistics with the requisite specificity and must be dismissed.

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” A to dismiss under Fed. R. Civ. P. 12(b)(6) may be granted if a court concludes that the plaintiff has failed to set forth fair notice of what the claim is and the grounds upon which it rests that make such a claim plausible on its face. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

*3 Although a complaint does not require detailed factual allegations, it must contain enough well-pleaded facts to show that the claim is facially plausible. This “allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The plaintiff must plead enough facts to “raise a reasonable expectation that discovery will reveal evidence of the necessary element,” *Twombly*, 550 U.S. at 556. Although all well-pleaded factual allegations must be accepted as true, the court may disregard any legal conclusions couched as factual allegations. *Id.*; *Iqbal*, 556 U.S. at 678; *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). If the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not “show[n]” – “that the pleader is entitled to relief.” *Iqbal*, 556 U.S. at 679.

Plaintiffs’ Complaint fails to separate out the liability for each defendant. Instead, it lumps Defendants together as

a group and asserts general common factual allegations against all of them. Count One, for example, contains 24 different allegations of negligence that vary widely, from violation of OSHA regulations to failure to provide a safe work place to failure to properly train employees to failure to supervise to negligent hiring. Rather than specify which Defendants were responsible for which duties, the Complaint merely states that all Defendants were negligent in the enumerated ways. Without any additional guidance as to the Defendants themselves and what functions they performed, it is impossible to untangle Plaintiffs' specific theory of liability against each individual Defendant.

Courts in this district generally agree that this type of "group pleading" does not satisfy [Rule 8](#), because it does not place Defendants on notice of the claims against each of them. See, e.g., [Ingris v. Borough of Caldwell](#), No. 14-855, 2015 WL 3613499, at *5 (D.N.J. June 9, 2015) ("[T]o the extent Plaintiff seeks to lump several defendants together without setting forth what each particular defendant is alleged to have done, he has engaged in impermissibly vague group pleading."); [Shaw v. Housing Auth. of Camden](#), No. 11-4291, 2012 WL 3283402, at *2 (D.N.J. Aug. 10, 2012) (dismissing complaint because it failed to contain allegations showing how each defendant was liable and noting that "[e]ven under the most liberal notice pleading requirements of Rule 8(a), a plaintiff must differentiate between defendants." (citing [Pietrangelo v. NUI Corp.](#), No. 04-3223, 2005 WL 1703200 (D.N.J. July 20, 2005)); see also [H2O Plus, LLC v. Arch Personal Care Prods., L.P.](#), 2011 WL 2038775, at *2 (D.N.J. May 22, 2011) (holding that complaint did not violate [Rule 8](#) because while plaintiff "did lump the Arch Defendants together in the description of facts, looking to the Complaint and the attached exhibits as a whole clearly shows which claims are made against Arch PCP and which against Arch Chemicals."))

Had the Complaint described the nature of each entity Defendant and precisely what they were responsible for on the Ship, the Court might have been able to infer the theory of liability for each Defendant by comparing the specific role each played on the Swan Chacabucco with the list of duties allegedly breached.⁵ But the Complaint does not do even that. Holt Logistics, like the other named Defendants in the case, is identified only as a "business entity" with a registered place of business; the Complaint describes neither its line of work nor its function on the ship. Instead, eight named Defendants are collectively alleged to have "owned, leased, operated, occupied, maintained,

managed and/or otherwise controlled the Ship and/or the Port" and to have "maintained, managed, oversaw, directed, controlled, contracted for and/or participated in the operation of stevedoring and/or longshoring services on the Ship and/or at the Port." (SAC ¶ 11.) The "and/or" conjunction appears no less than five times in this single sentence, making it impossible to determine Plaintiffs' theory of liability for each Defendant – and for Holt Logistics in particular.

⁵ For example, had Plaintiffs identified Holt Logistics as the entity responsible for hiring and providing stevedores for work on the Ship, and another Defendant as the entity responsible for the day-to-day supervision of their work, it may have been possible to partially deduce, based on the list of alleged negligent conduct, some of the duties each defendant is alleged to have breached. The only thing that comes close is Plaintiffs' allegation that Holt Logistics and Inchape Shipping "were responsible for training, screening, certifying, hiring and/or providing crane operators and/or other persons involved in stevedoring and/or longshoring operations at the Port." (SAC ¶ 10.) But even this assertion continues to lump Holt Logistics together with an unconnected entity, Inchape Shipping, and asserts seven different duties that either Defendant or Inchape Shipping could have been responsible for. The allegation can hardly be said to narrow down Defendants' liability in this case.

^{*4} Contrary to Plaintiffs' contention (see Opp'n to Mot. to Dismiss [Docket Item 38] at 3), the mere fact that the Complaint recites the type of negligent conduct at issue does not place the parties sufficiently on notice of the claims against them. Even though the misconduct is alleged with some specificity, [Rule 8](#) is not satisfied because the allegations do not inform each Defendant of the particular claims against it. Moreover, lumping all defendants together for different misconduct fails to demonstrate each defendant's individual liability. Without pleading how, if at all, Holt Logistics was involved with the alleged conduct at issue, the Complaint lacks sufficient facts to draw a reasonable inference that Holt Logistics is actually responsible for any the negligence alleged. See [Phillips v. Cnty. of Allegheny](#), 515 F.3d 224, 232 (3d Cir. 2008) ("We caution that without some factual allegation in the complaint, a claimant cannot satisfy the requirement [under [Rule 8\(a\)\(2\)](#)] that he or she provide not only 'fair notice,' but also the 'grounds' on which the claim rests." (quoting [Twombly](#), 550 U.S. at 555)).

Nor is the Court persuaded by Plaintiffs' citations to [In re Riddell Concussion Reduction Litig.](#), 77 F.Supp.3d 422 (D.N.J. 2015) (Simandle, J.), and the two unpublished district court opinions, [Capitol Records LLC v. ReDigi Inc.](#), No. 12-95, 2014 WL 4354675 (S.D.N.Y. Sept. 2, 2014), and [Toback v. GNC Holdings, Inc.](#), No. 13-80526, 2013 WL 5206103 (S.D. Fla. Sept. 13, 2013), which have little weight in this Circuit. In [Riddell](#), this Court rejected an argument that the complaint violated Rule 8 by lumping all defendants together without specifying the alleged misconduct of each defendant, because it was "apparent" that the claims were asserted against all defendants "for their concerted conduct under the 'Riddell' brand." 77 F. Supp. 3d at 431. The Court emphasized that group pleading was permissible in that particular case because the defendants did not dispute their collective role in the manufacture, sale, and marketing of the product in question, and they were related entities operating under a single brand, accepting service as a single entity, and represented by the same counsel. [Id.](#) at 432. [Capitol Records](#) and [Toback](#) similarly involve closely related Defendants. See [Capitol Records](#), 2014 WL 4354675, at *3 (noting that the defendants were a small start-up and two corporate officers "who directed and controlled essentially all of its activities"); [Toback](#), 2013 WL 5206103 (holding that complaint satisfied Rule 8 despite referring to defendants – GNC Holdings, Inc., GNC Corp, General Nutrition Corporation, and General Nutrition Centers, Inc. – collectively as "GNC" because defendants were interrelated corporate defendants and demonstrated their understanding of the allegations against them).

[Riddell](#), [Capitol Records](#), and [Toback](#) provide no support that collective-style pleading is permissible in this case, since there are no allegations that Defendants acted jointly or in concert or are closely related corporate entities, such that conduct by one may be ascribed to the others.⁶ See [T.J. McDermott Transp. Co., Inc. v. Cummins, Inc.](#), 2015 WL 1119475, at *7 (D.N.J. Mar. 11, 2015) (holding Rule 8 was satisfied even though complaint failed to distinguish defendants' respective conduct because complaint specifically alleged that defendants formed a partnership).

⁶ The fact that Defendants are all represented by different counsel and that no other defendant has joined Holt Logistics' motion to dismiss is an additional indication that Defendants are independent and concerted action is lacking.

Because Counts One, Two, and Three all suffer from the same infirmity by asserting that the injuries sustained by Plaintiff "were caused by the carelessness and negligence of all Defendants," (SAC ¶23), and failing to allege any specific act of misconduct by Holt Logistics, the Complaint as a whole must be dismissed for failing to place Holt Logistics on notice of the claims against it.

*5 Count Two of the Complaint must additionally be dismissed because Plaintiffs have not pleaded sufficient facts to establish a plausible cause of action against Holt Logistics under the Longshore and Harbor Workers' Compensation Act. Specifically, the Complaint does not plead that Holt Logistics qualifies as a "vessel" for purposes of the LHWCA. (Mot. to Dismiss at 10-11; Reply in Supp. of Mot. to Dismiss [Docket Item 40] at 6-7.) Section 905(b) of the LHWCA codifies the exclusive remedy for longshoremen and permits an "action against [a] vessel as a third party" for injuries "caused by the negligence of [such] vessel." 33 U.S.C. § 905(b). The LHWCA, in turn, defines a "vessel" within the meaning of [section 905\(b\)](#) to include the "vessel's owner, owner pro hac vice, agent, operator, charter or bare boat charterer, master, officer, or crew member." 33 U.S.C. § 902(21).

A "vessel owner pro hac vice" is "one who assumes by charter or otherwise exclusive possession, control, command and navigation of the vessel for a specified period of time." [DeArmond v. Southwire Co.](#), 109 Fed. App'x 722, 724 (6th Cir. 2004) (internal quotations and citation omitted); [see also](#) [Bossard v. Port Allen Marine Serv., Inc.](#), 624 F. 2d 671, 672-73 (5th Cir. 1980) ("[T]he charterer takes over the ship, lock, stock and barrel, and mans her with his own people. He becomes ... the owner pro hac vice." (internal quotations and citation omitted)); [Irby v. Tokai Lines](#), No. 88-6890, 1990 WL 18880, at *3 (E.D. Pa. Feb. 23, 1990) (noting requirement of "exclusive possession, control, command, and navigation"). The term "vessel," in other words, encompasses "the ship's owner and the owner's agents." [Browning v. Safmarine, Inc.](#), No. 11-2436, 2012 WL 6089481, at 3 n.1 (D.N.J. Dec. 5, 2012).

This Court recently had occasion to explicate the duties of the "vessel" and the "pro hac vice owner" to an offloading stevedore under the LHWCA in [Jones v. Sanko Steamship Co.](#), ___ F. Supp. 3d ___, 2015 WL 8361745 (D.N.J. Dec. 8, 2015). The LHWCA requires that the liability of defendants be separately determined in light of their respective functions relating to the ship and its cargo. [Id.](#) at 7-8. Such an assessment of LHWCA duties for a particular defendant is not

viable where the plaintiff engages in group pleading against unrelated, disparate parties.

Count Two alleges only that all Defendants, including Holt Logistics, “owned, operated, managed, possessed and/or controlled the Ship which it operated in the navigable waters of the United States.” (*Id.* ¶ 24) (emphasis added). This assertion, however, does not rule out the possibility that Holt Logistics merely “controlled” the Ship. Generally speaking, “those who exercise control over a vessel for a particular purpose such as repairing, cleaning or unloading are not considered to be owners pro hac vice.” *DeArmond*, 109 Fed. App’x at 725. In *DeArmond*, the Sixth Circuit gave the example of a stevedore hired to unload a barge and who exercises control and dominion over the barge in order to do so, and noted that the stevedore was clearly not an owner pro hac vice. The Court explained that this was because even though a party may “control command and navigate the vessel while it is in their possession to accomplish the designated task, the owner of the vessel has not relinquished complete dominion and control of the vessel tantamount to a demise of the vessel.” *Id.* Because the Complaint fails to contain a well-pleaded factual allegation that Holt Logistics was the owner or owner pro hac vice of the Swan Chacabucco, Plaintiffs have not stated a plausible claim for relief under Count Two.

For all the reasons above, Defendant’s motion to dismiss will be granted in its entirety. The Court will, however, dismiss Plaintiffs’ claims against Holt Logistics without prejudice and permit Plaintiffs to file a motion to amend, along with a Proposed Amended Complaint which corrects the multiple deficiencies discussed herein. In so doing, the Court again emphasizes that it is not sufficient to fail to identify each defendant’s role and function or say that each of the defendants is responsible for everything. Plaintiffs must be careful to specify the basis (i.e., the factual grounds) for Defendant’s liability under each Count.

IV. THE COURT WILL DENY DEFENDANT’S MOTION FOR SANCTIONS

*6 Defendant argues that sanctions are warranted because there are no facts to support Plaintiffs’ claim that Holt Logistics was in any way liable for Sheeran’s injury. (Mot. for Sanctions [Docket Item 49-1], at 9-12; Reply in Support of Mot. for Sanctions [Docket Item 53], at 4-9.)

Federal Rule of Civil Procedure 11 requires an attorney to conduct a “reasonable inquiry” into the law and facts before filing a pleading with the court, and to certify that the

legal arguments contained therein are not being presented for any improper purpose and are not frivolous, and the factual contentions have or “will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.” Fed. R. Civ. P. 11(b)(1)-(3). By discouraging the filing of frivolous, unsupported, or unreasonable claims, and permitting sanctions to be imposed for violations, Rule 11 “seeks to strike a balance between the need to curtail abuse of the legal system and the need to encourage creativity and vitality in the law.” Fed. R. Civ. P. 11(c); *Gaiardo v. Ethyl Corp.*, 835 F.2d 479, 483-84 (3d Cir. 1987); *see also Lieb v. Topstone Indus. Inc.*, 788 F.2d 151, 157 (3d Cir. 1986); *Leuallen v. Borough of Paulsboro*, 180 F. Supp. 2d 615, 618 (D.N.J. 2002).

When evaluating whether conduct violates Rule 11, the Third Circuit applies a “reasonableness under the circumstances” standard, which is defined as “an objective knowledge or belief at the time of the filing of a challenged paper that the claim was well grounded in law and fact.” *Ford Motor Co. v. Summit Motor Prod., Inc.*, 930 F.2d 277, 289 (3d Cir. 1991). The wisdom of hindsight should be avoided, and the attorney’s conduct must be judged by “what was reasonable to believe at the time the pleading, motion, or other paper was submitted.” Fed. R. Civ. P. 11 advisory committee note; *Mary Ann Pensiero, Inc. v. Lingle*, 847 F.2d 90, 94 (3d Cir. 1988).⁷

⁷ The Court notes that Defendant has complied with the “safe harbor” provision of Rule 11, which requires a moving party to notify the party against which it seeks sanctions of its intention to move for sanctions, and allows the non-moving party 21 days to take remedial action before the court imposes sanctions. Fed. R. Civ. P. 11(c)(2); *see Hockley by Hockley v. Shan Enterp. Ltd.*, 19 F. Supp. 2d 235, 240 (D.N.J. 1998). Defendant sent a “safe harbor” letter together with a copy of the motion on September 18, 2015, 25 days before filing the instant motion with the Court. (See Sept. 18, 2015 Letter, Ex. 1 to Mot. for Sanctions [Docket Item 49-2].)

The Court does not find that the circumstances of this case meets the “high standard for imposing sanctions under Rule 11,” *Oswell v. Morgan Stanley Dean Witter & Co., Inc.*, 507 F. Supp.2d 484, 492 (D.N.J. 2007) (Simandle, J.). Counsel for Plaintiffs had a good-faith basis to believe that Defendant had a hand in controlling stevedoring activities at the site where Steven Sheeran was injured. In particular,

it was reasonable for counsel to believe that the operations of Sheeran's employer, Gloucester Terminals, LLC, at the Port of Gloucester, were being overseen by Holt Logistics. The N.L.R.B. decision, upon which counsel asserts he relied, describes the involvement of the Holt brothers and their various companies (including Holt Logistics) in operations in and around the Port of Gloucester, where the Swan Chacabucco was berthed. (Ex. 1 to Opp'n to Mot. for Sanctions [Docket Item 52-2].) The decision identifies Holt as the CEO of Gloucester Terminals, LLC, and also identifies an individual named Walter Curran who was hired by Holt and who "actively managed" the work of Gloucester Terminals, LLC. (*Id.* at 9.)

*7 Thus, Defendant's argument that Sheeran, who has already settled a claim with Gloucester Terminals, LLC, is barred from asserting a claim against Holt Logistics,⁸ holds no water. Counsel for Plaintiffs had a good-faith basis to believe that Holt Logistics was not Sheeran's employer "via common ownership" with Gloucester Terminals, LLC, but rather an entity that owned and supervised Sheeran's employer and its stevedoring operations. Counsel thus had a reasonable basis to believe that Sheeran's settlement with his direct employer did not extinguish his rights under the LHWCA to file suit against Holt Logistics.

8 Specifically, Defendant argues that because a plaintiff who recovers against an employer under LHWCA worker's compensation scheme is barred from suing that employer under the LHWCA for further damages, see 33 U.S.C. §§ 904(b), 905(a), counsel lacked a good-faith basis to file suit against Holt Logistics because Sheeran had already settled a claim with Gloucester Terminals, LLC, and Holt Logistics was his co-employer. (Opp'n to Mot. for Sanctions, at 11-12.)

Counsel's belief that Holt Logistics should remain in the action is also not unreasonable under the high Rule 11 standard. Counsel notes that depositions taken after the Complaint continue to raise the possibility that Gloucester Terminals, LLC was managed by Holt Logistics, because certain higher-level employees seemed to be affiliated with both entities. While depositions from individuals employed by Gloucester Terminals, LLC, identified John Florkiewicz and P.J. Inskeep as the stevedore manager and Vice President of Gloucester Terminals, LLC, respectively, both had Holt Logistics-affiliated email addresses. (Quigley Dep., Ex. 3 to Opp'n to Mot. for Sanctions [Docket Item 52-4], at

39:8-41:9; Mountney Dep., *Id.* Ex. 4 [Docket Item 52-5], at 20:8-21:2.) Moreover, an operations representative for Defendant Inchape Shipping identified Florkiewicz and Inskeep as being from Holt Logistics, and additionally testified that he copied several people from Holt Logistics on every email that he sent regarding vessel movements and berthing details. (Hubbard Dep., *Id.* Ex. 2 [Docket Item 52-3], at 53:20-56:7.)

Given the evidence indicating a close relationship between Defendant and Sheeran's employer, it was not palpably unreasonable for Plaintiffs' counsel to believe that Holt Logistics maintained some supervisory role over the stevedoring work of Gloucester Terminals, LLC. Although counsel may not have had a precise understanding of Holt Logistics' responsibilities, it was not unreasonable for counsel to infer that Defendant had a separate duty to ensure the safety of the premises, and that the duty was breached.

"Rule 11 is intended for only exceptional circumstances," Gaiardo, 835 F.2d at 483, and a "district court must exercise discretion and sound judgment in dealing with the myriad methods with which lawyers may abuse the judicial process." Eavenson, Auchmuty & Greenwald v. Holtzman, 775 F.2d 535, 540 (3d Cir. 1985). While it remains to be seen whether Plaintiffs can plead sufficient facts to plausibly establish Holt Logistics' liability in this case, the Court is satisfied that counsel did not drag Holt Logistics into this case based solely upon unsupported, unreasonable, and frivolous allegations. Defendant's motion for sanctions is denied.

IV. CONCLUSION

For the foregoing reasons, the Court will grant Defendant's motion to dismiss. The dismissal is without prejudice to Plaintiffs' right to file a motion for leave to file an Amended Complaint within fourteen (14) days of the date of entry of this Order, accompanied by a Proposed Amended Complaint which remedies the deficiencies discussed herein. The Court will deny Defendant's motion for sanctions, but takes this opportunity to remind counsel that any attempt to replead against Holt or any other defendant is governed by the requirements of Rule 11(b), including that the legal claims are warranted by existing law and that the factual contentions have evidentiary support or (if specifically identified) will likely have evidentiary support after a reasonable opportunity for further investigation or discovery, see Rule 11(b)(2) & (3), Fed. R. Civ. P. An accompanying Order will be entered.

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TAB 43

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United States District Court, D. New Jersey,
Camden Vicinage.

Michael SICH and Ellen
Bitterlich, his wife, Plaintiffs,
v.
PFIZER PHARMACEUTICAL, Pfizer
Incorporated, et al., Defendants.
Civil No. 1:17-cv-02828 (RBK/KMW)
|
Signed 10/04/2017

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OPINION

ROBERT B. KUGLER, United States District Judge

*1 This matter arises upon defendant Pfizer Incorporated's ("Defendant") motion to dismiss plaintiffs Michael Sich and Ellen Bitterlich's ("Plaintiffs") suit for failure to state a claim upon which relief can be granted. *Fed. R. Civ. P. 12(b)(6)*. For the reasons set forth in the opinion below, this motion is **GRANTED WITHOUT PREJUDICE**, and Plaintiffs are permitted to submit an amended complaint as to only the claims arising under the New Jersey Products Liability Act ("PLA") within 14 days.

I. BACKGROUND

Plaintiffs allege that Defendant's drug, Dep-Medrol, caused Mr. Sich severe physical injuries. *See Compl. at 1*. In February 2015, Mr. Sich visited Reconstructive Orthopedics where a physician's assistant administered an injection of Dep-Medrol in his left knee. *Id.* Later that month, Mr. Sich returned to Reconstructive Orthopedics for an appointment with Dr. Scott Schoifet and received a second injection. *Id. at 2*. Within hours, Mr. Sich began experiencing symptoms including elevated temperature, sensitivity, swelling, rashes, and hives. *Id.* Within a week, Mr. Sich underwent open *debridement*

and two operations, and required seventeen days of inpatient treatment. *Id.* Plaintiffs then sued in New Jersey State Court, but Defendant removed the case on diversity grounds. *See Notice of Removal* (Doc. No. 1). Mr. Sich alleges that the "medication supplied by Defendant [] was defective" and caused his injuries. *Id.*

Plaintiffs seek relief under a number of theories. *See Compl.* First, Plaintiffs allege a design defect, a failure to warn, and manufacturing defects under the PLA. *Id.*; N.J.S.A. § 2A:58C. Second, Plaintiffs allege breach of actual and implied warranties, negligence, and "other causes of action allowed by law." *Compl. at 4*. Finally, Plaintiffs allege loss of consortium on behalf of Ms. Bitterlich. *Id. at 5*.

II. STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows a court to dismiss an action for failure to state a claim upon which relief can be granted. When evaluating a motion to dismiss, "courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). In other words, a complaint survives a motion to dismiss if it contains sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

To make this determination, a court conducts a three-part analysis. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the court must "take note of the elements a plaintiff must plead to state a claim." *Id.* (quoting *Iqbal*, 556 U.S. at 675). Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id. at 131* (quoting *Iqbal*, 556 U.S. at 680). Finally, "where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Id.* (quoting *Iqbal*, 556 U.S. at 680). This plausibility determination is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. A complaint cannot survive where a court can only infer that a claim is merely possible rather than plausible. *Id.*

III. ANALYSIS

***2 Plaintiffs' Strict Products Liability, Negligence, Breach of Implied Warranty, and Loss of Consortium Claims Are Subsumed by the PLA.**

The PLA is “both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products.” *In re Lead Paint Litigation*, 924 A.2d 484, 436-37 (N.J. 2007) (citing N.J.S.A. § 2A:58C-1(b)(3) (defining “product liability action”)). The statute’s reach includes “any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty.” N.J.S.A. § 2A:58C-1(b)(3).

Here, Plaintiffs allege injuries sustained as a result of Mr. Sich’s use of *Depo-Medrol*. See Compl. The PLA, as a result, applies—this is a products liability case. But “negligence, strict liability and implied warranty have been consolidated into a single product liability cause of action” by the PLA. *Clements v. Sanofi-Aventis, U.S. Inc.*, 111 F. Supp. 3d 586, 596 (D.N.J. 2015) (“New Jersey law no longer recognizes breach of implied warranty, negligence, and strict liability as viable separate claims for harms deriving from a defective product.”); *Fid. & Guar. Ins. Underwriters, Inc. v. Omega Flex, Inc.*, 936 F. Supp. 2d 441, 446-51 (D.N.J. 2013); *Green v. Gen. Motors Corp.*, 709 A.2d 205, 209 (N.J. Super. 1998). Furthermore, the PLA subsumes loss of consortium claims arising in products liability contexts. *Chester v. Boston Sci. Corp.*, No. CV 16-02421, 2017 WL 751424, at *4 (D.N.J. Feb. 27, 2017). Therefore, Plaintiffs’ strict products liability, negligence, breach of implied warranty, and loss of consortium claims are subsumed by the PLA and must be dismissed as a matter of law.

Because the PLA subsumes these claims, it would be futile to include them in the amended complaint.

Plaintiffs PLA and Breach of Express Warranty Claims Fail to Meet The Fed. R. Civ. P. 12(b)(6) Pleading Standard and Must be Dismissed Without Prejudice With Leave to Amend.

A. Design Defect

Under New Jersey law, the plaintiff must show that the “product was defective, that the defect existed when the product left the defendant’s control, and that the defect caused injury to a reasonably foreseeable user.” *Feldman v. Lederle*

Labs., 97 N.J. 429, 449 (N.J. 1984); see *Donlon v. Gluck Grp., LLC*, No. 09-5379, 2011 WL 6020574, at *3 (D.N.J. Dec. 2, 2011). The plaintiff must demonstrate that the “product [was] manufactured as intended but the design render[ed] the product unsafe.” *Pollander v. Desimone BMW of Mt. Laurel, Ltd.*, No. A-3204-10T3, 2012 WL 127563, at *3 (N.J. Super. Ct. App. Div. Jan. 18, 2012). Plaintiffs must also provide—pursuant to a risk-utility analysis—an alternative design that is both practical and feasible. *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 560-61 (N.J. 1998); *Schraeder v. Demilec (USA) LLC*, No. 12-6074, 2013 WL 5770970, at *2 (D.N.J. Oct. 22, 2013).

Plaintiffs have failed to reach this bar. Plaintiffs have alleged that as a result of a defect in the product, “including its sterility and/or formulation, Plaintiff Michael Sich was injected with toxic substances and injured.” Compl. at 3. That is not enough—Plaintiffs have failed to plead facts that satisfy each of the necessary elements of a design defect claim, they have simply alleged injury.

B. Failure to Warn

***3** A manufacturer is liable for harm caused by a failure to warn if the product does not contain an adequate warning or instruction. N.J.S.A. § 2A:58C-4. A warning is adequate if it is “one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product.” *Id.*; *Banner v. Hoffman-La Roche Inc.*, 891 A.2d 1229, 1236 (N.J. Super. App. Div. 2006) (cert. denied, 921 A.2d 447 (N.J. 2007)).

Plaintiffs’ allegations fail to meet this standard. Plaintiffs allege that “[a]s a direct and proximate result of” Defendant’s failure to warn, “Plaintiff Michael Sich was injected with toxic substances and was injured.” Compl. at 3. Plaintiffs offer nothing further, and thus do not reach the requisite plausibility requirement.¹ *Iqbal*, 556 U.S. at 680.

¹ Because Plaintiffs have not alleged or pleaded *any* facts related to the warning label, this Court does not reach the questions of (1) whether the learned intermediary doctrine applies and if Mr. Sich’s healthcare provider was adequately warned of any relevant dangers; and (2) whether the warning label is protected by the rebuttable presumption of adequacy afforded to FDA-approved prescription medication under the PLA. N.J.S.A. § 2A:58C-4.

C. Manufacturing Defect

A manufacturing defect exists if a product “deviated from the design specification, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae.” [N.J.S.A. § 2A:58C-2\(a\)](#). A plaintiff must prove “that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff, [who must be] a reasonably foreseeable or intended user.” [McMahon v. Gen. Dynamics Corp.](#), 933 F. Supp. 2d 682, 695 (D.N.J. 2013) (citing [Myrlak v. Port Authority of N.Y. and N.J.](#), 723 A.2d 45, 52 (N.J. 1999)).

Plaintiffs have alleged that as a “direct and proximate result of ... manufacturing defects including its sterility and/or formulation, Plaintiff Michael Sich was injected with toxic substance and was injured.” Compl. at 3. Plaintiffs have not, however, explained how the drug differed from the requisite standard or how it was allegedly defective. This claim thus lacks the factual support that it needs to reach the *Twombly* / *Iqbal* plausibility standards—conclusory statements are not enough. [550 U.S. at 570](#); [556 U.S. at 680](#).

D. Breach of Express Warranty

An express warranty is an “affirmation of fact or promise made by the seller ... which relates to the goods and becomes part of the basis of the bargain.” [N.J.S.A. § 12A:2-313\(a\)](#).

Plaintiffs must allege: (1) that Defendant made an affirmation, promise, or description about the product; (2) that this affirmation, promise, or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description. [Mendez v. Shah](#), 28 F. Supp. 3d 282, 294 (D.N.J. 2014); [Fid. & Guar. Ins. Underwriters, Inc.](#), 936 F. Supp. 2d at 451.

Plaintiffs have failed to present an affirmation, promise, or description about the product made by Defendant. They have additionally failed to allege how this missing affirmation, promise, or description became a part of the basis of the bargain for the product, nor how the product ultimately did not conform to that affirmation, promise, or description. As such, the breach of express warranty claim constitutes a categorical allegation and nothing more. [Iqbal](#), 556 U.S. at 678.

IV. CONCLUSION

*4 Because the complaint as pleaded does not present facts, accepted as true, that give rise to any plausible entitlement to relief, Defendant's motion to dismiss is **GRANTED WITHOUT PREJUDICE** and Plaintiffs are permitted 14 days to submit an amended complaint correcting the deficiencies noted above.

All Citations

Not Reported in Fed. Supp., 2017 WL 4407930

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TAB 44

 KeyCite Yellow Flag - Negative Treatment
Distinguished by [Snyder v. Farnam Companies, Inc.](#), D.N.J., May 26, 2011
2008 WL 4936982

Only the Westlaw citation is currently available.
United States District Court, D. New Jersey.

[Sean SIMMONS](#), Plaintiff,

v.

STRYKER CORPORATION, et al., Defendants.

Civil Action No. 08-3451 (JAP).

|

Nov. 17, 2008.

West KeySummary

1 [Sales](#)  Breach and elements thereof in general

Anesthetics device buyer's breach of warranty claim against device manufacturer was devoid of any factual matter to support the existence of an express warranty. Buyer alleged that manufacturer warranted that their device was a safe and effective ambulatory drug delivery system, and was fit, safe, and effective and proper for the purpose for which it was to be used. However, buyer identified no source whatsoever of any alleged warranty. [N.J.S.A. 12A:2-313](#).

[19 Cases that cite this headnote](#)

Attorneys and Law Firms

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[Kim M. Catullo](#), Gibbons P.C., Newark, NJ, for Defendants.

OPINION

[JOEL A. PISANO](#), District Judge.

*1 This is a products liability action involving a device referred to as a "pain pump" that delivers controlled infusions

of local anesthetics to a surgical patient. Presently before the Court is a motion by Defendants Stryker Corporation and Stryker Sales Corporation ("Defendants") to dismiss Counts One and Counts Five through Twelve of Plaintiffs Complaint pursuant to Rule 12(b)(6). Defendants argue that these claims, with the exception of Count Nine, are subsumed by Plaintiff's other claims under New Jersey's Product Liability Act, [N.J.S.A. § 2A:58C-1 et seq.](#) As to Count Nine, breach of express warranty, Defendants argue that Plaintiff has failed to adequately plead such a claim.

Plaintiff does not oppose Defendants' motion as to Counts One, Five, Six, Seven Eight, Ten, Eleven and Twelve. In fact, Plaintiff "agrees that [all of the challenged Counts except Count Nine] are due to be dismissed." Pl. Mem. at 4.¹ Consequently, those Counts shall be dismissed with prejudice. With respect to Count Nine, Plaintiff contends that the claim has been sufficiently pled and further argues that, if the Court were to find otherwise, he should be given leave to amend his complaint after the close of discovery. For the reasons below, the Court finds that Count Nine fails to state a claim upon which relief can be granted, and, consequently, Defendants' motion to dismiss that count shall be granted.

¹ Plaintiff's Memorandum of Law in Opposition to Defendants' Motion to Dismiss does not contain page numbers; therefore, the Court refers to the page number assigned by the electronic filing system that appear in the header.

In the breach of express warranty claim set forth in Count Nine Plaintiff alleges that "[t]he Defendants expressly warranted that their pain pump was [a] safe and effective ambulatory drug delivery system" and also warranted the pain pump to be "fit, safe, and effective and proper" for the purpose for which it was to be used. Compl. ¶ 75, 76. The complaint further alleges that "the pain pump ... did not conform to these express representations because it causes serious injuries to consumers when inserted." *Id.* at ¶ 76. Plaintiff contends that Defendants should have known that these representations were false, that the medical community as well as Plaintiff relied upon these warranties, and that Defendants breached the express warranties because the pain pump was not safe and fit for its intended use. Defendants assert that these allegations are insufficient to state a claim and Count Nine should be dismissed. Def. Reply at 3.

Referring to the Supreme Court's recent "formulation of the pleading standard" in *Bell Atlantic Corp. v. Twombly*,²

the Third Circuit has noted that stating a claim “requires a complaint with enough factual matter (taken as true) to suggest the required element.” *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir.2008) (internal quotations omitted, alteration in original). The court noted that **Federal Rule of Civil Procedure 8(a)(2)** requires “a showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the ... claim is and the grounds on which it rests,” and, therefore, a complaint requires at least some factual allegations to make this “showing.” *Phillips*, 515 F.3d at 232 (alterations in original) (quoting *Twombly*, 127 S.Ct. at 1964). However, this does not mean that a heightened pleading requirement now applies—the *Twombly* decision clearly indicated that the Court was not adopting or applying a “heightened pleading standard,” 127 S.Ct. at 1974 (“[W]e do not require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face”),—and this Court shall not apply one. Nevertheless, under the liberal pleading standard, the Court finds Count Nine to be insufficient.

² 550 U.S. 554, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

*2 As noted by the Defendants, under New Jersey law, an express warranty can be created by the following:

- (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
- (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
- (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

N.J.S.A. § 12A:2-313. Defendants contend that Count Nine fails to state a claim because it does not contain sufficient factual allegations about the nature of the express warranty. The Court agrees. Plaintiff's breach of warranty claim is devoid of any “factual matter” to support the existence of an express warranty. Rather, there is simply a conclusory recitation of the elements of the claim. Plaintiff has alleged no facts to suggest that an express warranty existed.

Other courts have dismissed similar claims under similar circumstances. For example, in *Heisner ex rel. Heisner v.*

Genzyme Corp., 2008 WL 2940811 (N.D.Ill., July 25, 2008), much like the instant case, the plaintiff alleged that the defendant “expressly warranted to Plaintiff by and through statements made ... orally and in publications, package inserts, and other written materials ... that [the product at issue] was safe, effective, fit and proper for its intended use,” and further alleged that he relied on this warranty and that the warranty was false. The court dismissed the plaintiff's claim, finding that the plaintiff in that case

has offered nothing more than a formulaic recitation of the elements required to prevail on a claim and has alleged no facts at all that suggest an express warranty existed. Plaintiff has not specified any particular affirmation, promise, description, or sample that formed part of the basis of his bargain with Defendant. He thus fails to put the Defendant on notice as to the substance of his claim.

Id. at *8–9 (noting that some courts have “required that plaintiffs at least mention the particular promise or description that allegedly gave rise to an express warranty” and citing *Johnson v. Brown & Williamson Tobacco Corp.*, 122 F.Supp.2d 194, 206 (D.Mass.2000), where the court found that a breach of express warranty claim was insufficient when it stated only that the defendant extended an express warranty through its “advertising, marketing and other efforts.”).

Notably, the breach of warranty claims that were dismissed in both *Heisner* and *Johnson* contained *more* factual detail than the claim in the present case. In each of those cases the plaintiffs generally identified the source of the alleged warranty (e.g., publications, package inserts, advertising), although this general identification was not sufficient to survive a motion to dismiss. Here, Plaintiff identifies no source whatsoever of any alleged warranty. Thus, the Court finds Plaintiff's breach of express warranty claim in this case to be inadequately pled and Count Nine is dismissed without prejudice. Plaintiff, if he wishes to amend his complaint to allege facts sufficient to support his breach of express warranty claim, shall be permitted 20 days to do so in light of this Opinion.³ An appropriate Order follows.

³ The Court denies Plaintiff's request to have until after the close of discovery to amend his Complaint. Plaintiff simply has provided no explanation whatsoever as to why this is necessary or appropriate in this case.

All Citations

Not Reported in F.Supp.2d, 2008 WL 4936982

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TAB 45

2020 WL 1237394

Only the Westlaw citation is currently available.

United States District Court,
N.D. Texas, Dallas Division.

Raymon J. SWEEZY, IV

v.

C.R. BARD INCORPORATED et al.

CIVIL ACTION NO. 3:19-CV-2172-S

|

Signed 03/12/2020

Attorneys and Law Firms

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MEMORANDUM OPINION AND ORDER

KAREN GREN SCHOLER, UNITED STATES DISTRICT JUDGE

*1 This Order addresses Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s (collectively, "Defendants") Motion for Summary Judgment [ECF No. 95]. For the following reasons, the Court grants in part and denies in part the Motion.

I. BACKGROUND

Plaintiff Raymon Sweezy ("Plaintiff") was treated with Defendants' Recovery Inferior Vena Cava Filter ("Filter") on June 28, 2008. Mot. 4. Sometime thereafter, Plaintiff's filter allegedly migrated and perforated his Inferior Vena Cava ("IVC"). *See id.*; *see also* Resp. in Opp. to Mot. for Summ. J. ("Resp.") 6. Plaintiff brings claims for Strict Products Liability – Information Defect (Failure to Warn) (Count II); Strict Products Liability – Design Defect (Count III); Negligence – Design (Count IV); Negligence – Failure to Warn (Count VII); Negligent Misrepresentation (Count VIII); Negligence Per Se (Count IX); Breach of Express Warranty (Count X); Fraudulent Misrepresentation (Count XII); and Fraudulent Concealment (Count XIII).¹ *See* ECF No. 1. Plaintiff also seeks punitive damages. *Id.* at 3.

¹ Plaintiff withdrew his claims for Strict Products Liability – Manufacturing Defect (Count 1) and Negligence – Manufacture (Count V). This Order, therefore, does not address those claims.

Defendants filed the pending Motion on February 17, 2020, seeking summary judgment on all of Plaintiff's claims (including his claim for punitive damages). Mot. 1. For the following reasons, the Court grants the Motion with respect to Plaintiff's Negligence Per Se (Count IX) and Fraudulent Concealment (Count XIII) claims and denies the Motion as to the remaining claims.

II. ANALYSIS

A. Negligence Per Se (Count IX)

"Negligence per se is a tort theory whereby courts use statutes or regulations to define the standard of reasonably prudent conduct." *Monk v. Wyeth Pharm., Inc.*, Civ. A. No. SA-16-CV-1273-XR, 2017 WL 2063008, at *8 (W.D. Tex. May 11, 2017) (quoting *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002)). "Texas courts ... refuse to recognize a cause of action for negligence per se based on violations of the [FDCA] and FDA regulations." *Id.* (quoting *Holland v. Hoffman-La Roche, Inc.*, No. 3-06-CV-1298-BD, 2007 WL 4042757, at *3 (N.D. Tex. Nov. 15, 2007)); *see also* *Jackson v. Tae Jin Kim*, No. 2:02-CV-200, 2004 WL 6040969, at *4 (E.D. Tex. Sept. 27, 2004) (citing *Baker v. Smith & Nephew Richards, Inc.*, No. 95-58737, 1999 WL 811334, at *8 (Tex. Dist. June 7, 1999), *aff'd on other grounds sub. nom.*, *McMahon v. Smith & Nephew Richards, Inc.*, No. 14-99-00616-CV, 2000 WL 991697 (Tex. App.—Houston

[14th Dist.] July 20, 2000, no pet.). Plaintiff does not dispute that his negligence per se claim is based on Defendants' alleged violations of the FDCA and FDA regulations. *See* Resp. 50. Accordingly, the Court grants summary judgment as to Plaintiff's negligence per se claim.

B. Fraudulent Concealment (Count XIII)

Under Texas law, "fraudulent concealment is not an independent cause of action, but is rather a tolling provision to prevent the defendant from relying upon a statute of limitations period as an affirmative defense." *Seismic Wells, LLC v. Matthews*, Civ. A. No. 5:15-CV-148-C, 2015 WL 11027778, at *4 (N.D. Tex. Sept. 11, 2015) (citing *Thompson v. Barnard*, 142 S.W.2d 238, 241 (Tex. Civ. App.—Waco 1940), *aff'd*, 158 S.W.2d 486 (Tex. 1942)). The Court, therefore, grants summary judgment as to Plaintiff's fraudulent concealment claim. Plaintiff has, however, preserved his right to assert fraudulent concealment as a defense to limitations at trial. *See Smith v. Palafox*, Civil No. EP-15-CV-00201-DB-RFC, 2016 WL 10515973, at *7 (W.D. Tex. Sept. 28, 2016) (citing *Nichols v. Smith*, 507 S.W.2d 518, 520 (Tex. 1974)).

C. Remaining Claims

*2 With respect to the remaining claims, the Court finds that Plaintiff has established that there is a genuine issue of material fact so that a reasonable jury might return a verdict in his favor. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). Therefore, the Court denies the Motion as to those claims.

III. CONCLUSION

For the reasons discussed above, the Court grants the Motion as to Counts IX and XIII and denies the Motion as to all other Counts.

SO ORDERED.

All Citations

Slip Copy, 2020 WL 1237394

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TAB 46

 KeyCite Yellow Flag - Negative Treatment

Distinguished by [Quashie v. Olympus America, Inc.](#), N.D.Ga., June 19, 2018

2017 WL 2255776

Only the Westlaw citation is currently available.

United States District Court,
N.D. Georgia, Atlanta Division.

Emma THORNTON, Plaintiff,
v.

ASTRAZENECA PHARMACEUTICALS
LP; and AstraZeneca LP, Defendants.

CIVIL ACTION NO. 1:17-CV-653-SCJ

Signed 05/15/2017

Attorneys and Law Firms

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Federal Rule of Civil Procedure 8(a)(2) “requires only ‘a short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to ‘give the defendant fair notice of what the ... claim is and the grounds upon which it rests.’” [Bell Atl. Corp. v. Twombly](#), 550 U.S. 544, 555 (2007). On a motion to dismiss, courts must “accept[] the [factual] allegations in the complaint as true and constru[e] them in the light most favorable to the plaintiff.” [Boyd v. Warden, Ala. Dep’t of Corrections](#), — F.3d —, 2017 WL 1856071, at *5 (11th Cir. May 9, 2017). Critically, conclusory allegations are not entitled to that assumption of truth—“*legal conclusions must be supported by factual allegations.*” [Bishop v. Ross Earle & Bonan, P.A.](#), 817 F.3d 1268, 1270 (11th Cir. 2016) (emphasis added).

“While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” [Twombly](#), 550 U.S. at 555. To avoid dismissal, “a complaint,” in other words, “must ‘state a claim to relief that is plausible on its face,’ meaning it must contain ‘factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.’” [Bishop](#) 817 F.3d at 1270 (quoting [Ashcroft v. Iqbal](#), 556 U.S. 662, 678 (2009)). The following narrative, culled from Thornton’s complaint, reflects those review principles.

ORDER

HONORABLE STEVE C. JONES, UNITED STATES DISTRICT JUDGE

*1 Before the Court in this products liability case is Defendants’ Motion to Dismiss plaintiff Emma Thornton’s complaint for failure to state a claim. Doc. 18.¹

¹ All record citations are to the electronic docket unless otherwise noted, and all page numbers are those imprinted by the Court’s docketing software.

I. STANDARD OF REVIEW

Normally the Court narrates the factual background driving a particular case before it explains the review lens to be applied. The centrality of this matter’s lens to that narration requires reversing the normal order of things.

II. BACKGROUND

“Emma Thornton ingested [Nexium](#),” a drug manufactured by Defendants² (doc. 7 at 4) that is “used to reduce the production of [stomach] acid,” “as prescribed and/or directed by her physician starting in 2007.” [Id.](#) at 1-2 (first amended complaint). In doing so, she “read and followed the directions regarding the use of [Nexium](#),” [id.](#) at 2, and used it “for its intended purposes and for purposes that Defendants expected,” though Thornton never says what those purposes are or what Defendants expected. [Id.](#) at 25. By 2011, Thornton believes, she developed “[Chronic Kidney Failure](#) ... as a result of her use of ...[Nexium](#).” [Id.](#) “To date,” and despite much scientific evidence pointing to a link between proton pump inhibitors (PPIs) and kidney damage, “over-the-counter PPIs lack detailed risk information for” a kidney injury named [acute interstitial nephritis](#) (AIN). [Id.](#) at 11. Over-the-counter and prescription PPIs both meanwhile “lack detailed risk information for” [chronic kidney disease](#). [Id.](#) At no point does Thornton say what “risk information”

the [Nexium](#) she actually consumed (which she also never identifies) contained.

² Defendants argue that Thornton defines [Nexium](#) as “every [stomach acid reducer] that is or ever has been on the market,” and thus that she “fails to identify the allegedly defective product.” Doc. 18-1 at 3. Although it is true that Thornton’s complaint is, quite often, not a model of clarity, it is a stretch to say that she fails to identify the product she claims caused injury.

The entire complaint is about [Nexium](#). The only factual allegations (of which there are precious few) are about [Nexium](#). One loose sentence in a thirty-four page, 154 paragraph, five count complaint defining “[Nexium](#)” (see doc. 7 at 1, ¶ 2) cannot change those overarching, unignorable facts. Whether Thornton identified what version of [Nexium](#) (over-the-counter or prescription, injectable or oral, etc.) she ingested is a different, and relevant, question. But Thornton indubitably claims that [Nexium](#) caused her kidney problems.

*2 The complaint’s next section, titled “Summary of the Case” (all of the facts above reside in the “Introduction”), describes how [Nexium’s](#) active ingredient operates, and how it can cause kidney damage. See, e.g., doc. 7 at 5, ¶¶ 24-30. Thornton then alleges that Defendants hold new drug applications for four versions of [Nexium](#), but, again, never says which type she took. Id. at 5-6. She alleges that Defendants “market and sell [Nexium](#)” with certain drug control numbers, speculates that Defendants could, if they wanted to, alter advertisements without FDA approval, asserts legal conclusions, and lists “a multitude of studies ... linking the dangers” of long term use of drugs like [Nexium](#) and kidney damage. Id. at 5-7.

The “Factual Allegations” section begins with approximately forty paragraphs of facts like “21 million Americans used one or more prescription PPIs, such as [Nexium](#), in 2009,” and “a study published in the Journal of the American Medical Association found that PPI use was independently associated with a 20 – 50% higher risk of” [chronic kidney disease](#). Doc. 7 at 9, 11. None of those paragraphs include allegations about Thornton, the [Nexium](#) she actually took, the warnings on her [Nexium](#), or anything relating to *her*. The remainder of the “Factual Allegations” section (six paragraphs) contains legal conclusions that play no role in evaluating the complaint’s sufficiency. [Twombly](#), 550 U.S. at 555.

Up next is a “Federal Requirements” section. Doc. 7 at 15. It contains two more conclusions, followed by a single paragraph with thirty-two subparts listing various federal statutes and regulations, none of which contain a single factual allegation. Id. at 15-20; see, e.g., id. at 16 (“[Nexium](#) is misbranded pursuant to 21 U.S.C. § 352 because, among other things, its labeling is false or misleading.”). “Federal Requirements” then gives way to a short section arguing that Defendants should be estopped from pleading a statute of limitations defense and in favor of tolling the applicable limitations period in any case. Id. at 20-21. But argument, like legal conclusions, cannot help complaints state claims.

Sandwiched in the middle of all that argument, however, lie two facts: (1) that Thornton “was not aware of the connection between the use of Proton Pump Inhibitors [like [Nexium](#)] and [chronic kidney disease](#) until April of 2016, when [she] saw a television commercial identifying [a] link,” and (2) she had no “access to, [n]or actually receive[d] any studies or information recognizing the increased risk of [chronic kidney disease](#) with [Nexium](#) use or have any discussions with her Doctor that there was an association between her [chronic kidney disease](#) and [Nexium](#) use. Doc. 7 at 21. That, however, is the end of Thornton’s foray into facts.

At paragraph 101, the complaint begins to outline Thornton’s five claims.³ Perhaps unsurprisingly, the beginning of each count contains a paragraph that states “[t]he paragraphs above are incorporated by reference hereto as if set forth at length.” See, e.g., doc. 7 at 21. None of the counts include any additional factual allegations.

³ Those five are: (1) negligence, pled “in the broadest sense available under law to include pleading same pursuant to all substantive law that applies to this case,” whatever that means; (2) strict products liability; (3) breach of express warranty; (4) breach of implied warranty; and (5) fraudulent misrepresentation. Doc. 7 at 21-30. Thornton also seeks punitive damages. Id. at 31.

III. ANALYSIS

Defendants ply several dismissal-justifying arguments. First, they contend that Thornton’s claims are barred by Georgia’s two-year statute of limitations for bodily injury tort claims. Doc. 18-1 at 5-6. Diagnosed with [kidney disease](#) in 2011, Thornton, they say, fails to plead adequate facts showing that she reasonably discovered within the last two years that [Nexium](#) caused her half decade-old injury. Id. at 6.

*3 Defendants also point out that the complaint is a shotgun pleading that “fail[s] ... to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests.” *Id.* at 8. In particular, Defendants complain about Thornton’s reincorporation paragraphs, her all-encompassing definition of Defendants,⁴ and her alleged refusal to “identify what actions [Defendants] took as opposed to the litany of third-parties Plaintiff included in her definition of Defendants.” Doc. 18-1 at 9. In fact, say Defendants, Thornton’s complaint is not personalized at all. Instead, it is a “one-size-fits-all-form complaint that Plaintiff’s counsel uses against AstraZeneca in other lawsuits.” *Id.* at 10 (citing *Barnes v. AstraZeneca LP*, No. 1:17-cv-142-ODE, doc. 1 (N.D. Ga. Jan. 12, 2017)). “The result,” they say, “is an impersonal account of purported issues with PPIs generally and only sparse references to any injury allegedly sustained by Plaintiff here.” *Id.*

⁴ The term “Defendants,” says Thornton, shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint-venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

Doc. 7 at 3.

Moving on to Thornton’s actual claims, Defendants insist that each fails for lack of supporting facts. Her strict product liability claim perishes because she never alleges how *Nexium* was defectively manufactured, identifies a design defect, or reveals the substance of any inadequate warning. Doc. 18-1 at 16-19. Thornton’s negligence claim, say Defendants, fails for the same reason. *Id.* at 19. Meanwhile, her fraud claim fails to plead the circumstance constituting fraud with particularity, and her warranty claims never say what warranties Defendants made. *Id.* at 21-22.

Defendants insist that, at bottom, Thornton, by not identifying “products, conduct, or causality ... fails to plead the most basic facts necessary to support a claim against AstraZeneca.” Doc. 18-1 at 11. They accordingly urge dismissal, with prejudice, for failure to state a claim.

In response, Thornton declines to engage with the substance of Defendants’ arguments. To her, she “[c]learly” satisfies Rule 8’s pleading requirements and filed within the two year statute of limitations. Doc. 20 at 2. She devotes two pages of her brief (one third of the document) to detailing the standard of review for motions to dismiss (*id.* at 4-5), and ends by adding that “clearly [Thornton] presented facts to identify her prescription use of *Nexium*, the defects in labeling and shortcomings of the Defendants in properly warning Plaintiff of the risks associated with the use of *Nexium*, the causal link between *Nexium* and *chronic kidney disease*, and the date when her kidney injury was diagnosed.” *Id.* at 5. Thornton never asks for leave to amend in the event the Court agrees with Defendants.

Every pleading-based attack avenue Defendants press has merit. First, Thornton’s complaint plainly qualifies as a shotgun pleading. See *Strategic Income Fund, L.L.C. v. Spear, Leeds & Kellogg Corp.*, 305 F.3d 1293, 1295 (11th Cir. 2002) (“The typical shotgun complaint contains several counts, each one incorporating by reference the allegations of its predecessors....”); *see also id.* (127 paragraph, nine count complaint qualified as shotgun pleading). And since Thornton has already amended once and thus had an opportunity to cure her shotgun defect, the Court arguably could dismiss her complaint on those grounds. See *Byrne v. Nezhat*, 261 F.3d 1075, 1133 (11th Cir. 2001) (overturned on other grounds) (“[I]f, in the face of a shotgun complaint, the defendant does not move the district court to require a more definite statement, the court, in the exercise of its inherent power, must intervene *sua sponte* and order a repleader. Implicit in such instruction is the notion that if the plaintiff fails to comply with the court’s order—by filing a repleader with the same deficiency—the court should strike his pleading or, depending on the circumstances, dismiss his case and consider the imposition of monetary sanctions.”).

*4 Even if the complaint had no form-based shortcomings, no claim contains sufficient factual allegations to survive. As Defendants note, of 154 paragraphs, fewer than 10 (Defendants say five) “are dedicated to the specific circumstances of” Thornton. Doc. 18-1 at 10. And never does she tether her *Nexium* ingestion to her kidney troubles more securely than by blithely insisting that she suffered the latter “as a result of” the former. Doc. 7 at 2. Even at the pleading stage something more than that must exist in order for the case to survive a 12(b)(6) motion.

Defendants correctly observe that the complaint in this case mirrors that in Barnes except for six words. Doc. 18-1 at 10. Such extensive overlap raises significant questions about specific causation. Although a plaintiff might plead general causation via non-personalized allegations, it is hard to imagine how someone like Thornton or Barnes could show that a product caused their specific injury based on general allegations of any kind. Put differently, one might be able to show that a drug has the ability to cause heart attacks, but only allegations suggesting that you took the drug and that it in fact underlay your heart attack could suffice to show specific cause. Since causation, both general and specific, is an element of each of Thornton's claims, that inability alone merits dismissal. Were that not the case, each claim pled also contains other essential elements for which Thornton pleads no facts at all.

A. Strict Product Liability

To establish strict liability, the Plaintiff must show that “the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.” O.C.G.A. § 51-1-11(b)(1). “The existence of a defect is crucial, because a manufacturer is not an insurer against all risks of injury associated with its product.” Giordano v. Ford Motor Corp., 165 Ga.App. 644, 645, 299 S.E.2d 897 (1983).

Goodson v. Boston Sci. Corp., No. 1:11-CV-3023-TWT, 2011 WL 6840593, at *4 (N.D. Ga. Dec. 29, 2011). Defects can come in one of three flavors: manufacturing, design, or warning.

At no point does Thornton allege any facts revealing how the Nexium she took deviated from its intended design (manufacturing flaw). Nor does she identify a design defect. Instead, she concludes that “Defendants designed ...Nexium in a defective and unreasonably dangerous condition.” Doc. 7 at 25. But conclusions cannot undergird a plausible claim.

Thornton's attempt to plead a warning claim—Nexium contained “inadequate warnings”—fares no better. Doc. 7 at 25. It is nothing more than a string of legal conclusions unsupported by factual allegations. As such, it too cannot survive.

B. Negligence

Thornton's negligence claim contains similar flaws.

To state a cause of action for negligence in Georgia, the following elements are essential: (1) A legal duty to conform to a standard of conduct raised by the law for the protection of others against unreasonable risks of harm; (2) a breach of this standard; (3) a legally attributable causal connection between the conduct and the resulting injury; and, (4) some loss or damage flowing to the plaintiff's legally protected interest as a result of the alleged breach of the legal duty.

Fletcher v. Water Applications Distribution Grp., Inc., 333 Ga. App. 693, 696 (2015).

As discussed above, Thornton never makes the causal connection required and that alone dooms her negligence claim. What's more, she includes no allegations that suggest the conduct of the two defendants in this case breached any of the twenty-seven legal duties she identifies. Instead, she conclusorily alleges that Defendants—which “include[s] any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint-venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf”—were “guilty of carelessness, recklessness, negligence, gross negligence and willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their proton pump inhibitor Nexium.” Doc. 7 at 3, 22. “At the risk of repetition (perhaps downright tedium),” Mathis v. United States, 136 S. Ct. 2243, 2251–52 (2016), conclusions cannot state claims. Only facts can. And Thornton includes none relevant to conduct by either defendant that illustrate the breach of a legal duty, much less that that breach caused her kidney injury (whose existence the Court has no reason to doubt). Her negligence claim thus fails.

C. Breach of Warranties (Express and Implied)

*5 Both of Thornton's warranty claims fare no better because she never identifies the warranties Defendants allegedly made. She vaguely states that Defendants "warranted that their products were safe for use," but that is little more than reciting the elements of the causes of action. Doc. 7 at 28. Her implied warranty claims are even worse. She states that Defendants "intended that **Nexium** be used in the manner that ... Thornton used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested." *Id.* at 29. That, once again, is a series of conclusions. Legally, her warranty claims are no different than Thornton declaring defendants "breached a warranty because they breached a warranty." Needless to say such a claim fails.

D. Fraudulent Misrepresentation

Thornton's final claim fails for the same reason—she pleads only conclusions. In the fraud context, that compounds her complaint's problems because **Federal Rule of Civil Procedure 9(b)** requires that parties "state with particularity the circumstances constituting fraud." But Thornton never even identifies any statements that were misrepresentations. Instead, she pleads that "Defendants fraudulently misrepresented that the daily use of **Nexium** was safe and effective," and that "Defendants made representations and failed to disclose material facts with the intent to induce consumers, including Plaintiff, and the medical community to act in reliance by purchasing and using the **Nexium** sold by Defendants." Doc. 7 at 31.

But what did Defendants say? When did they say it? What material facts did they fail to disclose? At no point in thirty-four pages and 154 paragraphs (more if you include subparts) does Thornton ever answer those questions, much less distinguish between defendants. Her "allegations of fraud are therefore insufficient under **Rule 9(b)**." *Brazil v. Janssen*

[Research & Dev. LLC, No. 4:15-CV-0204-HLM, 2016 WL 4844442, at *11 \(N.D. Ga. Mar. 24, 2016\).](#)

IV. CONCLUSION

Thornton's first amended complaint (doc. 7) tramples pleading requirements and fails to give Defendants, or the Court, notice of which facts are intended to support which claims for relief. Indeed, it includes practically no relevant facts at all. Instead, it spends 34 pages inveighing against **Nexium** without ever identifying which version of the product Thornton ingested, how that version was defective, or what defense conduct caused her injury. In short, it fails to state any viable claim.⁵

⁵ Because it fails to state a claim, the Court need not decide whether the two-year statute of limitations bars Thornton's claims. Given her 2011 kidney damage diagnosis, it well may. But one of the few facts that Thornton pleads—that she learned of the connection between **Nexium** and kidney problems in 2016 – casts some doubt on that conclusion. In view of the mountain of pleading deficiencies, and the fact intensive nature of a statute of limitations dispute, the Court declines to decide that issue at this stage.

Accordingly, Defendants' motion to dismiss is **GRANTED**. Doc. 18. This case is **DISMISSED WITH PREJUDICE**. The clerk is **DIRECTED** to enter judgment in accordance with **Fed. R. Civ. P. 58(a)** and close this case.

SO ORDERED, this 15th day of May 2017.

All Citations

Not Reported in Fed. Supp., 2017 WL 2255776

TAB 47

 KeyCite Yellow Flag - Negative Treatment
Distinguished by [Ontel Products Corporation v. Zuru, LTD](#), D.N.J., August 29, 2018

2008 WL 5381227

Only the Westlaw citation is currently available.
United States District Court, D. New Jersey.

Alberto TORRES–HERNANDEZ, Plaintiff,
v.

CVT PREPAID SOLUTIONS, INC., Defendant.

Civil Action No. 3:08-cv-1057-FLW.

|
Dec. 17, 2008.

Attorneys and Law Firms

[Bruce Heller Nagel, Elliott Louis Pell](#), Nagel Rice, LLP, Roseland, NJ, for Plaintiff.

[Steven Lawrence Menaker](#), Chasan, Leyner, Bariso & Lamparello, P.C., Secaucus, NJ, for Defendant.

OPINION

[WOLFSON](#), District Judge.

*1 Presently before the Court is a motion filed by Defendant CVT Prepaid Solutions, Inc. (“Defendant”) to dismiss Plaintiff Alberto Torres–Hernandez’s (“Plaintiff”) Complaint, in which Plaintiff, individually and on behalf of all others similarly situated, asserts a claim arising under the New Jersey Consumer Fraud Act, and common law claims for fraud and misrepresentation and unjust enrichment. Alternatively, Defendant argues that jurisdiction over this matter properly lies with the Federal Communications Commission (“FCC”). Generally, Plaintiff alleges that Defendant’s pre-paid calling cards did not provide the minutes advertised and paid for by consumers. For the reasons set forth herein, Defendants’ motion to dismiss for lack of subject matter jurisdiction is denied, and its motion to dismiss for failure to state a cause of action is granted. However, Plaintiff shall be given leave to re-plead and file an Amended Complaint.

I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Since Defendant moves to dismiss Plaintiff’s Complaint pursuant to [Fed.R.Civ.P. 12\(b\)\(6\)](#), all facts alleged in the complaint are assumed to be true. Plaintiff is a resident of New Brunswick, New Jersey. Compl. ¶ 6. Defendant is a Delaware Corporation and a nationwide provider of prepaid calling cards that are distributed and sold in New Jersey. *Id.* ¶¶ 5, 8.

Cardholders buy access to allotments of long distance telephone access via an automated computer system commonly referred to as a “platform.” *Id.* ¶ 14. The platform monitors certain data points, namely the stated value of the prepaid calling card, the relevant rate table, the origin and destination of the call. *Id.* A prepaid calling card is generally accompanied by a toll-free telephone number that the cardholder must use to place a long distance call, otherwise known as “plugging into the platform.” *Id.* Once the user has connected with the access number, the user will be prompted to enter his or her personal identification number (“PIN”) found on the front or back of the card. *Id.* After the platform verifies the PIN, the user is then asked to enter the number to which he or she wishes to connect. *Id.* The user, after entering the destination number, is notified via voice prompt as to the amount of minutes he or she has left on that particular calling card. *Id.* The gravamen of Plaintiff’s Complaint is that Defendant’s cards “virtually never provide the minutes advertised to consumers nor do they provide the minutes that the voice prompt indicates are available to the user.” *Id.* ¶ 15.

As a result, Plaintiff filed this action on January 14, 2008, in the New Jersey Superior Court, Middlesex County Vicinage. In his Complaint, Plaintiff alleges that “Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and/or otherwise released pre-paid calling cards into the stream of commerce.” Compl. ¶ 25. Pursuant to [28 U.S.C. 1446\(a\)](#), the matter was removed to this Court on February 28, 2008. Defendant asserts that federal jurisdiction is proper pursuant to the Class Action Fairness Act of 2005, [28 U.S.C. 1332\(d\)](#), which provides that this Court has original jurisdiction over any class action (1) involving a plaintiff class of 100 or more members; (2) in which the amount in controversy exceeds \$5,000,000; and (3) where at least one member of the plaintiff class is diverse from defendant. Thereafter, Defendant filed this Motion to Dismiss pursuant to [Federal Rule of Civil Procedure 12\(b\)\(1\)](#) and [12\(b\)\(6\)](#) on March 6, 2008.

II. DISCUSSION

A. Standard of Review 12(b)(1)

*2 When jurisdiction is challenged pursuant to Rule 12(b)(1), the plaintiff bears the burden of persuading the court that subject matter jurisdiction exists. *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir.1991). No presumption of truthfulness attaches to the allegations of the complaint insofar as they concern subject matter jurisdiction. *Mortensen v. First Federal Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir.1977). Should factual issues arise regarding subject matter jurisdiction, the court may consider exhibits outside the pleadings. *Id.* Indeed, “the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.” *Id.*

B. Standard of Review 12(b)(6)

When reviewing a motion to dismiss on the pleadings, courts “accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir.2008) (citation and quotations omitted). Recently, in *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court “retired” the language contained in *Conley v. Gibson*, 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that “a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Id.* at 1968 (quoting *Conley*, 355 U.S. at 45–46). Instead, the factual allegations set forth in a complaint “must be enough to raise a right to relief above the speculative level.” *Id.* at 1965. As the Third Circuit has stated, “[t]he Supreme Court's *Twombly* formulation of the pleading standard can be summed up thus: ‘stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest’ the required element. This ‘does not impose a probability requirement at the pleading stage,’ but instead ‘simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of’ the necessary element.” *Phillips*, 515 F.3d at 234 (quoting *Twombly*, 127 S.Ct. at 1965).

C. Primary Jurisdiction

Initially, Defendant asserts that this Court should defer to the Federal Communications Commission (“FCC”) and its interstate telecommunication expertise in the present matter

under the doctrine of primary jurisdiction. In response, Plaintiff argues that the case at bar is devoid of technical questions and potential regulatory conflicts, and as such, this Court may exercise jurisdiction.

Defendant's argument that this Court should defer to the FCC constitutes a challenge to this Court's subject matter jurisdiction. The Supreme Court, in *Far East Conference v. United States*, 342 U.S. 570, 574–75, 72 S.Ct. 492, 96 L.Ed. 576 (1952), expounded on the doctrine of primary jurisdiction:

*3 [A] principle, now firmly established, that in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over. This is so even though the facts after they have been appraised by specialized competence serve as a premise for legal consequences to be judicially defined. Uniformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure.

The doctrine applies “to claims properly cognizable in court that contain some issue within the special competence of an administrative agency.” *Global Naps, Inc. v. Bell Atlantic–New Jersey, Inc.*, 287 F.Supp.2d 532, 548 (D.N.J.2003). Thus, cases involving specific technical or policy considerations within an agency's area of expertise should be referred to the appropriate administrative agency. *MCI Communications Corp. v. American Telephone & Telegraph Co.*, 496 F.2d 214, 220 (3d Cir.1974). The doctrine ensures a “workable

relationship between the courts and administrative agencies wherein ... the court can have the benefit of an agency's views on issues within the agency's competence." *MCI Telecommunications Corp. v. Teleconcepts, Inc.*, 71 F.3d 1086, 1105 (3d Cir.1995).

Additionally, the possibility that a conflict may arise if a court were to decide a matter inextricably intertwined with an intensive regulatory scheme requires judicial abstention in such cases. *Cheney State College Faculty v. Hufstedler*, 703 F.2d 732, 736 (3d Cir.1983); *American Telephone*, 496 F.2d at 220 (finding that the doctrine was created to "avoid conflict between the court and an administrative agency arising from either the court's lack of expertise with the subject matter of the agency's regulation or from contradictory rulings by the agency and the court."). However, a court need not defer review in every cause of action that requires a court to deal with regulatory rules. *The Business Edge Group, Inc. v. Champion Mortgage Company, Inc.*, 519 F.3d 150, 154 (3d Cir.2007). Such cases may be handled by a district court if the issues before it can be resolved "using the plain language of the [regulations] and ordinary rules of construction." *Id.* (quoting *Advance United Expressways, Inc. v. Eastman Kodak Co.*, 965 F.2d 1347, 1353 (5th Cir.1992)).

Even though the Third Circuit has visited the issue of primary jurisdiction on several occasions, there remains "no fixed formula for determining whether the doctrine of primary jurisdiction applies." *Global Naps*, 287 F.Supp.2d at 549. It is more appropriate for a court to evaluate issues of primary jurisdiction on a case-by-case basis. Nonetheless, the *Global Naps* court adopted four factors that can guide a court's analysis in such inquiries:

*4 (1) Whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) Whether the question at issue is particularly within the agency's discretion; (3) Whether there exists a substantial danger of inconsistent rulings; and (4) Whether a prior application to the agency has been made.

Id. (citing *Oh v. AT & T Corp.*, 76 F.Supp.2d 551, 557 (D.N.J.1999)). This Court also turns to the resolution of other disputes over primary jurisdiction in the Third Circuit. For instance, in *American Telephone*, a group of communication carriers brought suit to compel telephone companies to provide interconnection services. 496 F.2d at 220. The Third Circuit found that the district court should have deferred to the FCC for two reasons: (1) the FCC had issued two separate rulings around the time of the dispute dealing with interconnection services; and (2) proceedings before the FCC had recently been initiated that dealt with the same issues raised by the plaintiffs. *Id.*

In the instant matter, Defendant directs the Court's attention to the FCC's broad, sweeping regulation of interstate communications, namely pre-paid calling cards. Specifically, Defendant cites to recent regulatory decisions rendered by the FCC concerning the pre-paid calling card industry. Def.'s Br. Pg. 6 (citing 21 FCC Rcd 7290 (2006) and 20 FCC Rcd 4826 (2005)). The crux of Defendant's argument is simple: this Court's adjudication of this matter could conflict and upset the FCC's expansive regulatory scheme over pre-paid calling cards. Although there is no pending hearing before the FCC concerning this specific issue, Defendant argue that pursuant to Section 201(b) of the Communications Act of 1934, the FCC provides Plaintiff with a more appropriate forum to adjudicate his claims. In response, Plaintiff charges "[t]here is no appreciable danger of inconsistent rulings; either consumers received the appropriate minutes on prepaid calling cards, or the converse is true." This Court agrees.

Applying the *Global Naps* factors, the Court finds that Plaintiff's Complaint is properly before this Court. Simply put, the case at bar requires this Court to determine whether Plaintiff and those similarly situated received what they bargained for. In arguing that this Court should defer to the FCC, Defendant does not list any pending hearings involving issues that if they were to be decided before this Court would give rise to a conflict with the current FCC regulatory scheme. Unlike *American Telephone*, where the FCC had made two previous rulings directly on point and another hearing was scheduled to deal with the contested issues in that case, no previous FCC ruling has been cited by Defendant that governs the specific issue in this case, namely the regulation of allegedly fraudulently advertised pre-paid calling cards and recourse for the average consumer. See 496 F.2d at 220. Instead, Defendant relies on broad FCC regulations that promulgate general administrative rules that have no bearing on the discrete issues in the case at bar. For example, *In re*

Vista Services Corp., 15 FCC Rcd 20646 (Oct. 18, 2000), an FCC ruling cited by Defendant, does not confer sole jurisdiction on the FCC with respect to the marketing of telecommunication providers, rather it states that the FCC may adjudicate claims under 201(b) of the Communications Act of 1934. The case at bar deals with issues arising from Defendant's supposed violation of the NJCFA, not 201(b).

*5 Moreover, Defendant's position on primary jurisdiction is untenable. Taken to its logical extreme, Defendant's proposed application of the doctrine would permit a pharmaceutical company to avoid negligence claims in federal court by invoking the Food and Drug Administration's authority (putting aside any preemption issues), or force a state court to defer consumer fraud actions against a commercial bank due to Federal Reserve oversight. Primary jurisdiction is an exceptional doctrine reserved for those technical cases that would conflict with specific federal regulations or pending agency hearings. It is not an alternate route for federally regulated businesses to take as a way to avoid civil litigation with consumer plaintiffs. Accordingly, Defendant's Motion to Dismiss for lack of subject matter jurisdiction is denied.

D. Plaintiff's NJCFA Claim

Defendant also challenges Plaintiff's Complaint on the ground that it fails to sufficiently state a cause of action under the NJCFA.¹ The Act is intended to protect consumers who purchase "goods or services generally sold to the public at large." *Marascio v. Campanella*, 298 N.J.Super. 491, 689 A.2d 852 (App.Div.1997). To state a claim under the NJCFA, a plaintiff must allege:

¹ In his Amended Complaint, Plaintiff needs to clarify whether this action is on behalf of consumers nationwide or only applies to New Jersey consumers. Such clarification is necessary to determine the applicability of the NJCFA to other plaintiffs as well as other choice of law issues.

"(1) unlawful conduct by the defendants; (2) an ascertainable loss on the part of the plaintiff; and (3) a causal relationship between the defendants' unlawful conduct and the plaintiff's ascertainable loss." [*Frederico v. Home Depot*, 507 F.3d 188, 202 (3d Cir.2007)] (citing *Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 647 A.2d 454 (1994)). The NJCFA defines unlawful practice broadly, as including but not limited to unconscionable commercial practice, deception, fraud, false promise, false pretense

misrepresentation, or knowing concealment. N.J.S.A. 65:8-2.

Kalow & Springnut, LLP v. Commencement Corp., No. 07-3442, 2008 U.S. Dist. LEXIS 48036, at *9-10, 2008 WL 2557506 (D.N.J. June 23, 2008) (citation omitted).

Because Plaintiff alleges violation² of the NJCFA, Plaintiff's Complaint must meet the heightened pleading requirements of Fed.R.Civ.P. 9(b). *Naporano Iron & Metal Co. v. American Crane Corp.*, 79 F.Supp.2d 494, 510 (D.N.J.2000) (finding that the plaintiff's NJCFA claim was subject to 9(b)'s heightened pleading standard); *Slim CD, Inc. v. Heartland Payment Sys.*, No. 06-2256, 2007 U.S. Dist. Lexis 62536, at *32, 2007 WL 2459349 (D.N.J. Aug. 22 2007) ("The pleading requirements of Rule9(b) apply to ... NJCFA claims as well as ... common law fraud claims."). Recently, this Court reiterated what must be alleged to satisfy the heightened pleading standard:

² Plaintiff does not state whether he purchased one card or multiple cards. Thus, this Court cannot determine whether Plaintiff alleges more than one violation of the NJCFA.

Pursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which [it is] charged." *Lum v. Bank of America*, 361 F.3d 217, 223-24 (3d Cir.2004). To satisfy this standard the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation. See *id.* at 224.

*6 *Kalow*, 2008 U.S. Dist. LEXIS 48036 at *10-11, 2008 WL 2557506 (quoting *Federico*, 507 F.3d at 200). This heightened pleading standard applies to all three prongs of an NJCFA claim. *Kalow*, 2008 U.S. Dist. LEXIS 48036 at *10, 2008 WL 2557506.

A properly plead NJFCA claim requires a plaintiff to allege "unlawful conduct by the defendants." Unlawful conduct or practices, as defined by the Act, consist of:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission

of any material fact with intent that others rely upon such concealment, suppression, or omission, in connection with the sale or advertise of any merchandise.

N.J.S.A. 56:8-2. In other words, unlawful practices fall into one of three general categories: (1) affirmative acts; (2) knowing omissions; and (3) regulation violations. *Federico*, 507 F.3d at 202 (citation omitted). When the alleged consumer fraud consists of an affirmative act, it is unnecessary for the plaintiff to prove that the defendant intended to commit an unlawful act. *Slim CD*, 2007 U.S. Dist. LEXIS 62536, at *32, 2007 WL 2459349. Under the NJCFA, an affirmative representation is “one which is material to the transaction and which is a statement of fact, found to be false, made to induce the buyer to make the purchase.” *Mango v. Pierce-Coombs*, 370 N.J.Super. 239, 851 A.2d 62 (App.Div.2004). By contrast, when the alleged consumer fraud is an omission, intent is an essential element of the charge. *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 691 A.2d 350 (1997). In *Kalow*, this Court found these allegations plead under the NJCFA as insufficient to withstand a motion to dismiss: “Defendant engaged in unfair, false, deceptive, and misleading practices, representations, and omissions in representing that it produced good quality software that business should rely upon and that it would stand behind software.” *Kalow*, 2008 U.S. Dist. LEXIS 48036 at * 11, 2008 WL 2557506. The *Kalow* complaint merely restated the language that defined an unlawful practice contained in the NJCFA’s statutory language and made fleeting reference to an alleged misrepresentation on the part of the defendant. *Id.*

Here, Plaintiff’s Complaint suffers from a similar defect as the allegations in *Kalow*, alleging, without specificity, that “Defendant concealed, that the amount of minutes advertised are in excess of the actual amount of minutes a user of their cards can actually utilize” and a recitation of the NJCFA’s statutory language.” Compl. ¶¶ 30–31. After reviewing Plaintiff’s Complaint, the Court finds no specific factual allegations, the what, where, and when of Defendant’s alleged misrepresentations, necessary to sustain a cause of action under the NJCFA. Hypothetically, Plaintiff’s allegations would need to indicate specific misrepresentations, such as Defendant selling calling cards that specifically advertised that they contained 120 minutes when in fact Defendant knew the card would only provide 100 minutes worth of calling time for the cardholder. With respect to the marketing

allegations, general allegations of concealment on the part of a defendant are insufficient to sustain an NJCFA claim. *Cooper v. Samsung Electronics America, Inc.*, No. 07–3853, 2008 WL 4513924, at *8 (D.N.J. Sept.30, 2008). Plaintiff fails to supply any details as to the character of the marketing and advertising materials. *See id.* (finding that a plaintiff’s consumer fraud claim was deficient when he failed to specify which marketing or advertising materials allegedly mislead him in his purchase of the defendant’s product).

*7 Moreover, Plaintiff’s Complaint is devoid of any allegations that would be sufficient to set forth the causal relationship between Defendant’s unlawful conduct and Plaintiff’s ascertainable loss.³ To properly plead a causal nexus, a plaintiff cannot rely on legal conclusions that fail to allege “when statements were made or when the plaintiffs were exposed to the statements.” In *Dewey v. Volkswagen*, the court provided an example of a sufficiently plead causal nexus:

³ Additionally, Plaintiff must plead a specific ascertainable loss. A sufficiently plead ascertainable loss is one with enough specificity as to give the defendant notice of possible damages. Thus, in *Seville Industry Machine Corp. v. Southmost Machinery Corp.*, 742 F.2d 786, 791 (3d Cir.1984), a plaintiff satisfied the ascertainable loss pleading requirements “by incorporating into the complaint a list identifying with great specificity the pieces of machinery that were the subject of the alleged fraud.” Further, in *Kalow*, this Court found sufficient an alleged dollar amount lost by the plaintiff when it was forced to purchase a different product upgrade provided by the defendant. 2008 U.S. Dist. LEXIS 48036, at *10, 2008 WL 2557506. Here, Plaintiff “incur[red] monetary expense and has suffered an ascertainable economic loss that includes the purchase price of the pre-paid calling cards and the difference in price between the purchase price of the pre-paid cards and the fair market value for the actual minutes plaintiff received for which Defendants are liable to Plaintiff for treble Plaintiff’s actual damages.” Compl. ¶ 35. Although there is no specific dollar amount alleged in Plaintiff’s Complaint, that level of specificity is not required by the case law and Rule 9(b). However, the fact that Plaintiff fails to allege which calling card denominations he purchased, e.g.. a

120 minute calling card, precludes Plaintiff from sufficiently pleading ascertainable loss. Thus, if Plaintiff properly pleads the other two elements of the NJCFA, Plaintiff will also be able to plead ascertainable loss.

For example, in order to demonstrate the required causal nexus, Plaintiffs might be expected to plead facts stating whether the allegedly fraudulent statements on the website were on the website at the time that any of the individual Plaintiffs were deciding whether to purchase a Volkswagen, and whether any of the Plaintiffs saw those statements on Volkswagen's website.

[558 F.Supp.2d 505 \(D.N.J.2008\)](#). Thus, allegations set forth in "broad-brush fashion" will not suffice. *Kalow*, 2008 U.S. Dist. LEXIS 48036, at *17, 2008 WL 2557506. Here, Plaintiff's alleges in conclusory fashion that "[a]s a direct and proximate result of the acts of consumer fraud set forth above, Plaintiff has purchased and used prepaid calling cards which caused him to incur monetary expense and has suffered an ascertainable economic loss." Compl. ¶ 35. At its most basic level, Plaintiff has failed to allege when he purchased his calling card(s), what he relied upon regarding the minutes he purchased and how many calling minutes he actually received. These allegations as to a causal nexus between Defendant's alleged unlawful practices and Plaintiff's ascertainable loss do not withstand a motion to dismiss. Accordingly, Plaintiff's NJCFA claim is dismissed without prejudice.

E. Plaintiff's Fraud and Misrepresentation Claim

Additionally, Defendant seeks the dismissal of Count Two for failure to comply with [Fed.R.Civ.P. 9\(b\)](#). Rule 9(b) requires "[i]n all averments of fraud ..., the circumstances constituting fraud ... shall be stated with particularity." [Fed.R.Civ.P. 9\(b\)](#). In *Lum v. Bank of America*, 361 F.3d 217, 223–24 (3d Cir.2004), the Third Circuit expounded on the heightened pleading standard imposed on allegations of fraud:

In order to satisfy [Rule 9\(b\)](#), plaintiffs must plead with particularity "the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir.1984). Plaintiffs may satisfy this requirement by pleading the "date, place or time" of the fraud, or through "alternative means of injecting precision and some measure of substantiation into their allegations of fraud."

Id. (holding that a plaintiff satisfied [Rule 9\(b\)](#) by pleading which machines were the subject of alleged fraudulent transactions and the nature and subject of the alleged misrepresentations). Plaintiffs also must allege who made a misrepresentation to whom and the general content of the misrepresentation. See [*Saporito v. Combustion Eng'g*, 843 F.2d 666, 675 (3d Cir.1988)]; *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658–59 (3d Cir.1998); *Klein v. General Nutrition Cos.*, 186 F.3d 338, 345 (3d Cir.1999).

*8 Thus, the nature or subject of the fraud, or an indication of who made the alleged representations and to whom, must be set forth in the plaintiff's pleadings. *A-Valey Engineers, Inc. v. Board of Freeholders of Camden*, 106 F.Supp.2d 711, 716 (D.N.J.2000). The Rule's heightened pleading requirements "gives defendants notice of the claims against them, provides an increased measure of protection for their reputations, and reduces the number of frivolous suits brought solely to extract settlements." *Naporano Iron & Metal Co. v. American Crane Corp.*, 79 F.Supp.2d, 494, 511 (D.N.J.2000). With respect to a class action claim, "less specificity is required when the complaint presents the claims of a class and individual identification of the circumstances of the fraud as to each class member would require voluminous pleadings." *Szczubelek v. Cendant Mortgage Corp.*, No. 00–1858, 2001 WL 34875217, at *3 (D.N.J. Jun.15, 2001). However, this less stringent standard does not obviate the need for a lead plaintiff to set forth specific factual misrepresentations as to his particular allegations. *Id.*

As to Count Two, Plaintiff merely alleges in his Complaint that "Defendant made these misrepresentations and actively concealed adverse information" and "Defendant omitted, suppressed or concealed material facts in order to increase the sales of the product." Compl. ¶¶ 39–40. Although [Rule 9\(b\)](#)'s strictures are less exacting for class action complaints, Plaintiff's vague, conclusory allegations as to Defendant's alleged fraudulent acts are insufficient. The Complaint contains no factual substantiation of alleged fraudulent acts taken on the part of Defendant, presumably the specific misrepresentation of actual minutes on Defendant's pre-paid calling cards that Plaintiff purchased. Moreover, no general time period in which the alleged misrepresentations took place is set forth anywhere in Plaintiff's Complaint. In sum, Plaintiff's allegations "suffers from the precise problems that [Rule 9\(b\)](#) aims to prevent," that is failing to give the defendant the appropriate notice of the claims alleged against him and the specific fraudulent acts underlying the plaintiff's pleadings. *Naporano*, 79 F.Supp.2d at 512. Accordingly,

Count Two of Plaintiff's Complaint is dismissed without prejudice.

F. Plaintiff's Unjust Enrichment Claim

Finally, Defendant moves to dismiss Plaintiff's unjust enrichment claim. Defendant contends that Plaintiff's unjust enrichment claim is simply derivative of the fraud claims set forth in Counts I and II, and as such, should be dismissed. In his Complaint, Plaintiff alleges that “[i]n accepting payment for prepaid phone cards which virtually never provide the minutes advertised to consumers, Defendant has been unjustly enriched.”

With respect to Defendant's assertion that Count Three is nothing more than a derivative claim of Counts One and Two, this Court disagrees. An unjust enrichment claim may be sustained independently as an alternative theory of recovery. *In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517, 544 (D.N.J.2004) (finding defendant's motion to dismiss plaintiff's unjust enrichment claim as premature even where other remedies at law were available to plaintiff); *see also United States v. Kensington Hosp.*, 760 F.Supp. 1120, 1135 (E.D.Pa.1991) (allowing plaintiff to assert an unjust enrichment claim as an alternative theory of recovery when plaintiff had asserted a cognizable contract claim in the same complaint). Thus, this Court must determine whether Plaintiff's allegations give rise to an unjust enrichment claim.

*9 At the onset, the Court notes that an unjust enrichment claim need not be pled with the same specificity as a claim sounding in fraud. Rather, the more liberal notice pleading standard of Fed. R. Civ. 8(a) applies. An unjust enrichment claim requires plaintiff to allege “(1) at plaintiff's expense (2) defendant received benefit (3) under circumstances that would make it unjust for defendant to retain benefit without paying for it.” *In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517, 544 (D.N.J.2004) (quoting *RESTATEMENT OF RESTITUTION* 1 (1937)). Further, “[t]he unjust enrichment doctrine requires that plaintiff show that it expected remuneration from the defendant at the time it performed or conferred a benefit on defendant and that the failure of remuneration enriched defendant beyond its contractual rights.” *VRG Corp. v. GKN Realty Corp.*, 135 N.J. 539, 554, 641 A.2d 519 (1994). However, New Jersey

law does not recognize unjust enrichment as an independent tort cause of action. *Cafaro v. HMC*, No. 07-2793, 2008 WL 4224801, at *12 (D.N.J. Sept.8, 2008) (finding that the plaintiffs' unjust enrichment claim should be dismissed because the allegations sounded in tort and not in quasi-contract). Rather, “unjust enrichment … requires that plaintiff show that it expected remuneration from the defendant at the time it performed or conferred a benefit on defendant.” *VRG*, 135 N.J. at 554, 641 A.2d 519. Thus, where a plaintiff asserts an unjust enrichment cause of action along with tort claims and there appear to be no allegations that the plaintiff expected or anticipated remuneration from the defendant, the unjust enrichment claim should be dismissed. *See Cafaro*, 2008 WL 4224801, at *12.

Here, the Court is unable to discern whether Plaintiff's unjust enrichment claim is based on a quasi-contractual or implied contractual relationship with the expectation of remuneration or is alleged as an independent tort cause of action. Plaintiff's Complaint contains two counts arising from fraudulent misrepresentations and an unjust enrichment claim that simply relies on the allegations set forth in Counts One and Two. Accordingly, this Court dismisses Count Three of Plaintiff's Complaint without prejudice.

G. Plaintiff's Request for Leave to File Amended Complaint

Plaintiff requests leave to amend his Complaint should the Court grant Defendant's motion to dismiss. Since Plaintiff may have sufficient information to properly allege an NJCFA, fraud and misrepresentation, and unjust enrichment claim, this Court will give Plaintiff leave to amend his Complaint.

III. CONCLUSION

For the foregoing, Defendant's Motion to Dismiss for lack of subject matter jurisdiction is denied. However, Plaintiff's Complaint is dismissed without prejudice and Plaintiff shall be given leave to re-plead and file an Amended Complaint within 30 days.

All Citations

Not Reported in F.Supp.2d, 2008 WL 5381227

TAB 48

2012 WL 6595732

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Michael WALTERS, Plaintiff,

v.

Richard J. CARSON, Matthew J. Ernades, Jr., North Hanover Township Board of Education, Johnson & Johnson, and McNeil-PPC, Inc., Defendants.

Civil No. 11-6545 (RBK/AMD).

Dec. 17, 2012.

Attorneys and Law Firms

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OPINION

[KUGLER](#), District Judge.

*1 This matter comes before the Court upon Plaintiff Michael Walters's ("Plaintiff") Amended Complaint against Defendant McNeil-PPC, Inc. ("Defendant") asserting claims of negligence, breach of implied and express warranties, and strict liability arising out of Plaintiff's use of certain over the counter medication manufactured and distributed by Defendant. Currently before the Court is Defendant's motion to dismiss Plaintiff's Amended Complaint for failure to state a claim upon which relief can be granted (Doc. No. 28). *See Fed.R.Civ.P. 12(b)(6)*. For the reasons stated below, Defendant's motion will be granted.

I. BACKGROUND¹

¹ When considering the sufficiency of the factual allegations in a plaintiff's complaint, the Court, for purposes of deciding a motion to dismiss under *Fed.R.Civ.P. 12(b)(6)*, assumes such allegations to

be true. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir.2009).

Plaintiff was formerly a custodian employed by the North Hanover Township Board of Education ("the Board"). Amended Compl. ¶ 7. In October 2009, Plaintiff began taking *Tylenol Arthritis*, a medication manufactured, marketed, distributed, and sold by Defendant. Amended Compl. ¶ 1; Def.'s Br. in Support of Mot. to Dismiss 1. Later that month, Plaintiff began experiencing stomach problems which caused him to miss work. Amended Compl. ¶ 11.

On November 6, 2009, Plaintiff received a letter from the business administrator of North Hanover Township Schools, Matthew J. Ernandes, Jr. ("Ernandes"). *Id.* at ¶ 12. The letter recommended to the Board and to Richard Carson ("Carson"), superintendent of the North Hanover Township School District ("the District"), that Plaintiff's contract with the District be terminated because Plaintiff had used ten of his twelve allotted sick days since July 1, 2009. *Id.* at ¶¶ 12, 13. The Board followed the recommendation and terminated Plaintiff's employment as of December 1, 2009. *Id.* at ¶ 14.

At some point in 2009 following his termination, Plaintiff learned that *Tylenol Arthritis* had been known to cause stomach problems in individuals taking the medication and that the manufacturer had ordered a recall. *Id.* at ¶ 15. Plaintiff alleges that the *Tylenol Arthritis* products he had purchased and used were part of the recall. *Id.*

Plaintiff's Amended Complaint states various federal and state law claims against Carson, Ernandes, and the District arising out of his termination. In addition, and the focus of the instant motion to the dismiss, the Amended Complaint asserts three causes of action against Defendant²: (1) negligence in the manufacture of *Tylenol Arthritis*; (2) breach of express and implied warranties in selling the "inherently defective" *Tylenol Arthritis*; and (3) strict liability for placing the allegedly defective product into the stream of commerce. Amended Compl. ¶¶ 22-31.³

² The Amended Complaint also names Johnson and Johnson in the claims concerning *Tylenol Arthritis*. Defendant explains that it is responsible for the "manufacture, marketing, distribution and sale of the product." Def.'s Br. in Support of Mot. to Dismiss 1. Defendant is a wholly owned subsidiary of Johnson & Johnson. McNeil Corp. Disclosure Statement 2 (Doc. No. 29).

3 The Court exercises supplemental jurisdiction over Plaintiff's state law claims as they form part of the same transaction or occurrence giving rise to Plaintiff's federal claims against the North Hanover Township School Board Defendants. *See 28 U.S.C. § 1337(b) (2006)*.

In its instant motion to dismiss under *Fed.R.Civ.P. 12(b)(6)*, Defendant argues that Plaintiff's negligence, implied warranty, and strict liability claims are subsumed by the New Jersey Products Liability Act ("the PLA") and that Plaintiff has failed to state a claim under the Act. Def.'s Br. in Support of Mot. to Dismiss 2. Defendant further asserts that Plaintiff fails to state a claim under New Jersey law for breach of express warranty. Def.'s Br. in Support of Mot. to Dismiss 7.

II. DISCUSSION AND ANALYSIS

A. Legal Standard

*2 *Federal Rule of Civil Procedure 12(b)(6)* allows a court to dismiss an action for failure to state a claim upon which relief can be granted. When evaluating a motion to dismiss, "courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir.2009) (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir.2008)). In other words, a complaint survives a motion to dismiss if it contains sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

To make this determination, a court conducts a three-part analysis. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir.2010). First, the court must "take note of the elements a plaintiff must plead to state a claim." *Id.* (quoting *Iqbal*, 556 U.S. at 675). Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* at 131 (quoting *Iqbal*, 556 U.S. at 680). Finally, "where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Id.* (quoting *Iqbal*, 556 U.S. at 680). This plausibility determination is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. A complaint

cannot survive where a court can only infer that a claim is merely possible rather than plausible. *Id.*

B. Negligence, Breach of Implied Warranty, and Strict Liability Claims

It is well established in this Circuit that the PLA creates an "exclusive statutory cause of action" for products liability claims asserted under New Jersey law. *See Kury v. Abbott Laboratories, Inc.*, No. 11-803, 2012 WL 124026 at *3 (D.N.J. Jan.17, 2012) (quoting *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir.1991)). That is, after the enactment of the PLA, "only a single product liability action remains" under New Jersey law and it is the sole method by which to bring such a claim. *Id.* (quoting *Tirrell v. Navistar Int'l, Inc.*, 248 N.J.Super. 390, 591 A.2d 643, 647 (N.J.Super.App.Div.1991), cert. denied, 126 N.J. 390, 599 A.2d 166 (1991); *see also id.* at ——3-4, 599 A.2d 166 (quoting *In re Lead Paint Litig.*, 191 N.J. 405, 924 A.2d 484, 503, 504 (N.J.2007)) ("[The PLA] generally subsumes common law product liability claims ... [and] ... encompass[es] virtually all possible causes of action relating to harms caused by consumer and other products.").

In this case, although he brings suit against the manufacturer and distributor of a consumer product like *Tylenol Arthritis* for alleged injuries caused by that product, Plaintiff has stated common law claims of negligence, breach of implied warranty, and strict liability. However, these common law causes of action are subsumed by the PLA. *See Kury*, 2012 WL 124026 at *3. Thus, Plaintiff's failure to assert his claim under the PLA is a fatal pleading deficiency. Accordingly, the Court will grant Defendant's motion to dismiss Plaintiff's negligence, breach of implied warranty, and strict liability claims as improperly pled.

C. Breach of Express Warranty Claim

*3 By its own terms, the PLA does not extend to claims for breach of an express warranty. *N.J.S.A. § 2A:58C-1(3) (2011)*.⁴ Instead, under New Jersey law, "in order to state a claim for breach of express warranty, [a plaintiff] must properly allege: (1) that [the defendant] made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." *Arlandson v. Hartz Mountain Corp.*, 792 F.Supp.2d 691, 706 (D.N.J.2011). When a plaintiff's express warranty claims relies merely on bald assertions "that fail to identify specific

affirmations or promises,” the claims cannot survive a motion to dismiss. *Id. at 707*. Similarly, a claim “devoid of factual matter” that simply states “a conclusory recitation of the elements of the claim” will be dismissed. *Simmons v. Stryker Corp.*, No. 08-3451, 2008 WL 4936982 at *2 (D.N.J. Nov.17, 2008).

4 That provision reads, in relevant part, “[p]roduct liability action means any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty.”

In support of his breach of express warranty claim, Plaintiff alleges only the following: “[Defendant] expressly and impliedly warranted that *Tylenol Arthritis* was merchantable, free from any defects, and reasonably fit for the foreseeable use and intended purposes for which it was sold” and that “[Defendant] breached [its] express and implied warranties in that the *Tylenol Arthritis* was inherently defective, hazardous, unsafe, not properly and reasonably merchantable, and unfit for its intended, ordinary and foreseeable use.” Amend. Compl. ¶¶ 23–24.

Simply stated, Plaintiff’s Amended Complaint does not contain sufficient factual allegations to support a claim for breach of an express warranty. Even if the Court accepts Plaintiff’s allegation that Defendant *expressly* warranted that *Tylenol Arthritis* was “merchantable,” “free from any defects,” and “reasonably fit for the foreseeable use and intended purposes for which it was sold,” nowhere does Plaintiff allege how that alleged warranty formed any part of the basis of his decision to purchase the product. Instead, Plaintiff’s claims are best characterized as “a conclusory recitation of the elements of the claim.” See *Simmons*, 2008 WL 4936982 at *2. Thus, because Plaintiff failed to allege adequately the elements of a breach of express warranty cause of action under New Jersey law, the Court must grant Defendant’s motion to dismiss.

III. CONCLUSION

For the reasons stated above, Defendant’s motion is **GRANTED**. An appropriate order shall issue today.

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